



Australian Government

Department of Health and Aged Care

Office of the Gene Technology Regulator

Application for Accreditation of an Organisation

Organisation for which accreditation is sought: (legal entity or trading name)

Click or tap here to enter text.

Is this application accompanied by an application for a declaration that certain information be treated as **Confidential Commercial Information (CCI)**?

Yes

No

Note: If your application contains Confidential Commercial Information, please contact the OGTR on 1800 181 030 (ask for the Application Entry Point section) or email ogtr.applications@health.gov.au

Time taken to complete this form:

Hours

Minutes

Enter

Enter

General instructions

Application for Accreditation

The completion of this form indicates your organisation is applying for accreditation of an organisation under the *Gene Technology Act 2000* (the Act) and, as applicable, corresponding state legislation. The Gene Technology Regulator (the Regulator) needs the information you provide in this form to assist in determining whether to accredit the organisation. If the information you provide is incorrect or incomplete the Regulator's decision about this application may be delayed or may result in the Regulator not granting the accreditation.

The Regulator may require you to provide additional information. If this is necessary, you will be notified of the additional information required.

If the Regulator accredits the organisation, the organisation will be obliged to comply with the conditions of accreditation.

Accuracy of information

The information you provide in this application must be true and accurate. The Act (and corresponding state law) provides for imprisonment and fines where a person gives information to the Regulator that the person knows to be false or misleading.

All sections, parts and questions must be completed unless otherwise directed on the form. If the spaces provided are not sufficient to set out the requested information, you should attach additional information and clearly mark on the attachment which section, part and question the information relates to. You should also indicate against the item that there is additional information attached, noting the attachment title/number and the page number(s).

Timeframes

Paragraph 16(1)(a) of the Gene Technology Regulations 2001 (the Regulations) and equivalent provisions in corresponding State law specifies the timeframe within which the Regulator must consider and decide on an application for accreditation. This timeframe is 90 working days after the day the application is received by the Regulator.

Applicants should note that days on which the decision-making process cannot proceed because the Regulator is awaiting additional information from the applicant do not count as part of the timeframe given above.

Please note that working days are Monday to Friday, between the hours of 09:00am and 05:00pm and exclude ACT public holidays.

Confidentiality

If you wish to make an application for a declaration that specifies information that is Confidential Commercial Information (CCI) for the purposes of the *Gene Technology Act 2000* and corresponding state law, you must complete a CCI application form available at www.ogtr.gov.au and forward it together with this application.

Ethics

The National Framework of Ethical Principles in Gene Technology 2012 (Ethics Framework) has been developed by GTECCC to provide a national reference point for promoting ethical conduct in gene technology. The Ethics Framework is available on the [OGTR website](#).

Personal Information

Personal information is collected by the OGTR to enable the Gene Technology Regulator to perform the functions set out under the Act. Personal information specified in this form is collected for the purpose of assessing applications under the Act and is handled in accordance with the Australian Privacy Principles set out in the *Privacy Act 1988*. More information can be accessed at the OGTR's Privacy and personal information [web page](#). The OGTR's privacy policy explains how the OGTR collects, stores, uses, and discloses personal information, including how a person may seek access to, or correct their personal information, and how a complaint about a breach of the Australian Privacy Principles can be made.

Authorisation

If submitting the application by post, Section 5 ('Declarations' page) must be signed by a person authorised to sign on behalf of the organisation. If this application is to be submitted via e-mail, please either:

- attach a scanned image of the form with wet signature visible in Section 5; or
- if the person transmitting the e-mail is authorised to sign the application, they can include a statement in their e-mail stating that they are a person duly authorised to sign the application; or
- the form can be attached to the e-mail after being digitally signed.

For further information

- The *Guidelines for the Accreditation of Organisations and Explanatory Information* document which can be found at www.ogtr.gov.au under Forms and Guidelines;
- Contact the Office of The Gene Technology Regulator by telephone on 1800 181 030 or e-mail at ogtr@health.gov.au.

Lodging the application

The completed application form can be lodged with the OGTR:

- **By mail** to the Office of The Gene Technology Regulator, MDP 54, GPO Box 9848, CANBERRA, ACT, 2601; or
- **By e-mail** to ogtr.applications@health.gov.au.

You are encouraged to retain a copy of your completed application.

Acknowledgement of receipt

If you have not received any communication acknowledging the receipt of your application within two weeks, please e-mail ogtr.applications@health.gov.au or telephone 1800 181 030.

Section 1: Organisation and Personnel Information

Part A: Status/type of Organisation

Question 1

Indicate below which of the following describes your organisation.

Note: Your response to this question is necessary to determine whether the Regulator will issue the accreditation under Commonwealth legislation or under corresponding State law. If unsure of the organisation's status, you should seek legal or other advice which will accurately identify the legal status of the organisation.

(a) a natural person, or

(b) an organisation

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

- A. 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

Note: Not all incorporated organisations are constitutional corporations. If in any doubt, applicants should seek legal or other advice.

Is the organisation a:

- Higher Education Institution
- Hospital
- Research Institute or similar
- A 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.
- A 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.
- A Constitutional Corporation which is none of the above

- None of the above. If you are none of the above, describe your organisation in the space provided below.

Click or tap here to enter text.

B. For an organisation which is NOT a constitutional corporation

Is the organisation a:

- Higher Education Institution
- Hospital
- Research Institute or similar
- A Commonwealth Department.
- A State Government Department.
- None of the above. If you are none of the above, describe your organisation in the space provided below.

Click or tap here to enter text.

Part B: Contact Information

Please provide contact details for the Organisation, the CEO, and the Primary and Secondary Contact Officers (The people who will receive OGTR correspondence)

Organisation Information

Organisation name: (Legal Entity name)	Enter Organisation Name
Organisation business name: (if different to legal name)	Enter Organisation Name
ABN:	Enter ABN
Postal address: (must include Suburb, State, Postcode and Country)	Enter Postal Address

CEO or equivalent

Personal title: e.g. Ms/Mr/Dr:	Choose an item.
Position title:	Enter position
Given name (or preferred given name):	Enter given name
Family name:	Enter family name
Phone number:	Enter phone number
Additional contact number (if applicable):	Enter phone number
Email address:	Enter email address
Additional email address (if applicable):	Enter email address
Postal Address: (must include Suburb, State and Postcode)	Enter postal address

Organisation Primary Contact Officer

This is the person who will be the main point of contact for the OGTR in relation to applications and other operational matters pertaining to the Gene Technology legislation.

Is the primary contact the same as the CEO Contact?
(if the same as the CEO, the 'physical location' details need to be provided below, but all other contact details do not need to be re-entered)

Yes

No

Personal title: e.g. Ms/Mr/Dr:	Choose an item.
Position title:	Enter position
Given name (or preferred given name):	Enter given name
Family name:	Enter family name
Phone number:	Enter phone number
Additional contact number (if applicable):	Enter phone number
Email address:	Enter email address
Additional email address (if applicable):	Enter email address
Postal address: (must include Suburb, State and Postcode)	Enter postal address
Physical location (include Level/Floor, Building Number/ Name and Street Address)	Enter physical location

Organisation Secondary Contact Officer

It is not mandatory to nominate a secondary contact person. If a person is nominated, they will be included in all written communications with the primary contact listed above and may be contacted by telephone for the same purposes.

Does the organisation wish to create a secondary contact?

Yes No

(if No – proceed to Section 2)

Is the secondary contact the same as the CEO Contact?
(if the same as the CEO, the ‘physical location’ details need to be provided below, but all other contact details do not need to be re-entered)

Yes No

Personal title: e.g. Ms/Mr/Dr:	Choose an item.
Position title:	Enter position
Given name (or preferred given name):	Enter given name
Family name:	Enter family name
Phone number:	Enter phone number
Additional contact number (if applicable):	Enter phone number
Email address:	Enter email address
Additional email address (if applicable):	Enter email address
Postal address: (must include Suburb, State and Postcode)	Enter postal address
Physical location (include Level/Floor, Building Number/ Name and Street Address)	Enter physical location

Section 2:

Accreditation Information

You may copy this application form where multiple copies of certain parts are required. If the same information is relevant to more than one IBC there is no requirement to repeat the information (and attachments) but you must clearly make reference to this in your answer(s) and clearly identify the relevant information (and attachment).

If there is insufficient space in the boxes provided, please include any additional information as an attachment. Note the attachment title/number and the page number(s) in the space provided and mark on the attachment which Section, Part and question the information relates to.

Part A: Suitability

Question 1

Has the organisation previously been accredited by the Gene Technology Regulator?

Yes	<input type="checkbox"/>	Go to question 2	No	<input type="checkbox"/>	Go to question 3
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Question 2

If the answer to question 1 is yes, please state whether the previous accreditation was cancelled, suspended or surrendered, or whether the period for which it was valid has expired.

Cancelled	Yes	<input type="checkbox"/>	Date	<input type="text" value="Click or tap to enter a date."/>	No	<input type="checkbox"/>
Suspended	Yes	<input type="checkbox"/>	Date	<input type="text" value="Click or tap to enter a date."/>	No	<input type="checkbox"/>
Surrendered	Yes	<input type="checkbox"/>	Date	<input type="text" value="Click or tap to enter a date."/>	No	<input type="checkbox"/>
Expired	Yes	<input type="checkbox"/>	Date	<input type="text" value="Click or tap to enter a date."/>	No	<input type="checkbox"/>

If you ticked yes for any of the above, please provide details.

Click or tap here to enter text.

Question 3

Has the organisation been convicted, within a period of ten years immediately before making this application, of an offence against a law of the Commonwealth, a State or a foreign country relating to the health and safety of people or the environment which is punishable by a fine of \$5000 or more?

Yes No

If yes, please provide details.

Click or tap here to enter text.

Question 4

Has the organisation ever had a licence or permit (however described) under a law of the Commonwealth, a State or a foreign country relating to the health and safety of people or the environment revoked, suspended or cancelled?

Yes No

If yes, please provide details.

Click or tap here to enter text.

Question 5

Is there any other information relevant to questions 1 - 4 that may assist the Regulator in making a decision about accreditation?

Yes No

If yes, please provide details.

Click or tap here to enter text.

Part B: Institutional Biosafety Committee (IBC)

Question 6

Does the organisation:

(a) have one or more IBCs established by the organisation?

Yes Complete Part C

No

(b) have arrangements in place to use one or more IBCs that were established by another accredited organisation?

Yes Complete Part D

No

If you answered '**Yes**' to both of the above options, please complete Part C and Part D.

If you answered '**No**' to all parts of question 6, please provide an explanation in the space provided below. **Note** that the Regulator may not be able to accredit this organisation.

Click or tap here to enter text.

Part C: Established IBC

This part asks for information about IBCs established by the applicant organisation.

If the applicant organisation has not established any IBCs, go to Part D.

Question 7

How Many IBCs has the organisation established?

Please answer Questions 8 to 12 to provide the Regulator with information about the IBC(s) established by the applicant organisation, and provide contact details for the Chair and Main Contact for the IBC.

If more than one IBC has been established:

- answer the questions for the IBCs as a group;
- where the answer to a question is “No” for one or more of the IBCs, please indicate which IBC(s) the “No” applies to in the box provided below the question;
- copy the IBC Contact Details page and complete for each IBC established (page 15)

Question 8

Does the membership of each IBC possess the collective technical and scientific expertise necessary to assess all the matters that are likely to be put to them by the applicant organisation?

Note: Expertise must include skills and experience to competently assess and advise on the identification and management of the risks associated with dealings with GMOs undertaken by the accredited organisation, and to advise on the containment of GMOs?

Yes

No

If no, please provide reasons.

Click or tap here to enter text.

Question 9

Does the membership of each IBC include at least one independent member?

Note: Unless otherwise agreed by the Regulator, an independent member is someone who could be reasonably regarded as being free of any business or other relationship, including a relationship of employment, with the applicant organisation that could materially interfere with the exercise of unfettered and independent judgement in contributing to decisions made by the IBC.

Yes

Please describe below how his member is independent to the organisation.

No

Please provide reasons below. (Here you may choose to describe how you believe a person, who does not meet the requirement for independence in the note above, is nevertheless independent).

Click or tap here to enter text.

Question 10

Does the organisation have appropriate indemnification for all members of the IBCs established by it?

Yes No

If no, please provide explanation.

Click or tap here to enter text.

Question 11

Do all IBC members consider this indemnification to be acceptable?

Yes No

If no, please provide explanation.

Click or tap here to enter text.

Question 12

Is there any other information relevant to Questions 7 – 11 that may assist the Regulator in making a decision about accreditation?

Yes No

If yes, please provide details.

Click or tap here to enter text.

IBC Contact Details

Name of IBC:

If contact details have been previously provided in this application, indicate the role containing the person's information and the remaining contact information does not need to be re-entered.

Chairperson of IBC

Personal title: e.g. Ms/Mr/Dr:	Choose an item.
Tick if contact details have already been provided	<input type="checkbox"/> CEO <input type="checkbox"/> Primary Contact <input type="checkbox"/> Secondary Contact
Given name (or preferred given name):	Enter given name
Family name:	Enter family name
Phone number:	Enter phone number
Additional contact number (if applicable):	Enter phone number
Email address:	Enter email address
Additional email address (if applicable):	Enter email address
Postal address: (must include Suburb, State and Postcode)	Enter postal address

Main Contact for the IBC

(The person who will receive all OGTR correspondence relating to the IBC)

Personal title: e.g. Ms/Mr/Dr:	Choose an item.
Tick if contact details have already been provided	<input type="checkbox"/> Chairperson (enter physical location below) <input type="checkbox"/> CEO (enter physical location below) <input type="checkbox"/> Primary Contact <input type="checkbox"/> Secondary Contact
Given name: (or preferred given name)	Enter given name
Family name:	Enter family name
Phone number:	Enter phone number
Additional contact number (if applicable):	Enter phone number
Email address:	Enter email address
Additional email address (if applicable):	Enter email address
Postal address: (must include Suburb, State and Postcode)	Enter postal address
Physical location (include Level/Floor, Building Number/ Name and Street Address)	Enter physical location

Part D: Access to IBC Established by Another Accredited Organisation

This part asks for information about IBCs established by another accredited organisation but will be accessed by the applicant organisation.

Question 13

How many IBCs, established by another accredited organisation, will the organisation be accessing?

Choose an item.

- (a) Please list the IBCs and their parent accredited organisation (ie. the organisation that has established and maintains the IBC). Add additional rows to the table if required.

IBC name	Parent accredited organisation (i.e. organisation that established the IBC)
Click or tap here to enter text.	Click or tap here to enter text.

- (b) Please provide confirmation that each organisation, whose IBC(s) are proposed to be used, has agreed to the applicant organisation using the IBC(s). This must be done by submitting a completed and signed copy of the declaration (Section 3, Part B, page 20) for each IBC.

If more than one IBC is being accessed

- answer questions 14 and 15 for the IBCs as a group
- where the answer to a question is “No” for one or more of the IBCs, please indicate which IBC(s) the “No” applies to in the box provided below the question

Question 14

Does the applicant organisation believe that the membership of the IBC(s) possess the collective technical scientific expertise necessary to assess all the matters that are likely to be put to it by the applicant organisation?

Note: Expertise must include skills and experience to competently assess and advise on the identification and management of the risks associated with dealings with GMOs undertaken by the accredited organisation, and to advise on the containment of GMOs?

Yes No

If no, please provide reasons.

Click or tap here to enter text.

Question 15

Is there any other information relevant to Part D that may assist the Regulator in making a decision about accreditation?

Yes No

If yes, please provide details.

Click or tap here to enter text.

Part E: Capacity to comply with accreditation conditions

Question 16

Does the organisation have the capacity to comply with the conditions of accreditation that will generally be applied to an accredited organisation, as outlined in the Regulator’s *Guidelines for the Accreditation of Organisations*?

Yes No

If no, please advise in what way(s) the organisation fails to comply with the *Guidelines* and what strategies are suggested to enable/maintain accreditation of the organisation, if granted.

Click or tap here to enter text.

Attachment list

(All attachments to the application form must be listed here).

Click or tap here to enter text.

Click or tap here to enter text.

Click or tap here to enter text.

Click or tap here to enter text.

Click or tap here to enter text.

Click or tap here to enter text.

Section 3: Declarations

Part A - Declaration of the organisation submitting this application

This declaration must be completed and signed by the CEO (or equivalent), or a person with the authority to sign on behalf of the organisation.

I DECLARE THAT:

- I am a person authorised to submit this form,
- to the best of my knowledge, the information supplied on this form and any other attachment(s) is not false or misleading,
- 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* and corresponding state law,
- by including my name on this form, it is deemed to be my signature for the purpose of this form.

Printed name:	Click or tap here to enter text.
Signature:	
Date:	Click or tap to enter a date.

Part B - Declaration of the organisation responsible for the IBC

This declaration needs to be completed if the organisation for which accreditation is sought intends to rely on the services of an IBC established by **another** organisation accredited by the Gene Technology Regulator (the other organisation). The CEO or equivalent of the other organisation (or delegate) must make the following declaration.

(1) Name of applicant organisation for which accreditation is being sought:

Click or tap here to enter text.

(2) Name of the IBC to be used:

Click or tap here to enter text.

(3) I declare that:

- I am authorised to sign on behalf of:

Click or tap here to enter text.

(other organisation name)

which is accredited by the OGTR (Accreditation number: [Click or tap here to enter text.](#))

- the information provided regarding the IBC named above (in this form and any relevant attachment[s]) is true and correct;
- the organisation I represent has agreed that the organisation, named at (1), may access the IBC named at (2);
- that the IBC named at (2) above has the collective technical scientific expertise to advise upon the work anticipated to be done by the Applicant named at (1) above;
- that there are appropriate indemnification arrangements for all members of the IBC covering the use of the IBC by the applicant organisation, and all the IBC members consider this indemnification to be acceptable;
- that the membership of the IBC named above includes at least one independent member; 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 corresponding state law.

Printed name:	<input type="text" value="Click or tap here to enter text."/>	Signature:	<input type="text"/>
Job title:	<input type="text" value="Click or tap here to enter text."/>	Date:	<input type="text" value="Click or tap to enter a date."/>