



Application for Accreditation of an Organisation

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

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

Yes No

Time taken to complete this form:

Hours		Minutes	
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

General instructions

Please print clearly.

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).

Please keep a photocopy of your application at the time of lodgement.

Help is available:

- The Guidelines for the Accreditation of Organisations (see Appendix 2 of the Office of the Gene Technology Regulator (OGTR) Handbook on the Regulation of Gene Technology in Australia – A user's guide to the *Gene Technology Act 2000* and corresponding state law);
- The Office of The Gene Technology Regulator website at www.ogtr.gov.au;
or
- Contact the Office of The Gene Technology Regulator on telephone 1800 181 030 or
- E-mail at ogtr@health.gov.au

This form must be lodged with the Gene Technology Regulator:

- At Level 1, Pharmacy Guild House, 15 National Circuit, BARTON, ACT 2600;
- By mail to Office of The Gene Technology Regulator, MDP 54, PO Box 100, WODEN, ACT, 2606; or
- By facsimile to the Office of The Gene Technology Regulator on (02) 6271 4202 (the original should follow by mail).

The completion of this form indicates your organisation is applying for accreditation of an organisation under the *Gene Technology Act 2000* and corresponding state law. 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.

The information you provide in this application must be true and accurate. The *Gene Technology Act 2000* (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.

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

If you wish to make an application for a declaration that specifies information that is confidential commercial information for the purposes of the *Gene Technology Act 2000* and corresponding state law, you must complete a confidential commercial information application form and forward it with this application.

Personal information is safeguarded by the *Privacy Act 1988*. This prevents the personal information contained in this form being used for other than accreditation, or other purposes permitted by the law.

The application must be signed by a person authorised to sign on behalf of the organisation.

Section 1:

Organisation and Personnel Information

Status/type of Organisation

Question 1 Is this application being made by:

(a) a natural person, or

(b) an organisation

If the application is by an organisation, 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 licence 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.

1. A constitutional corporation i.e. a trading, foreign or financial corporation within the meaning of paragraph 51(xx) of the Constitution.

Note: Most companies are likely to be constitutional corporations. If in any doubt, applicants should seek legal or other advice.

Yes

No

2. A Commonwealth authority.

Yes No

If a Commonwealth authority, indicate by ticking the appropriate box which of the below best describes your status.

(a) a body corporate established for a public purpose by or under an Act;	<input type="checkbox"/>
(b) a company in which a controlling interest is held by any one or more of the following together:	
(i) the Commonwealth;	<input type="checkbox"/>
(ii) a body covered by paragraph (a);	<input type="checkbox"/>
(iii) a body covered by either of the above subparagraphs.	<input type="checkbox"/>

3. A State Government Agency:

Yes No

If a State Government Agency, indicate by ticking the appropriate box which of the below best describes your status.

(a) the Crown in right of a State;	<input type="checkbox"/>
(b) a State Government Department;	<input type="checkbox"/>
(c) an instrumentality of a State (including a body corporate established for a public purpose by or under a law of a State);	<input type="checkbox"/>
(d) a company in which a controlling interest is held by any one of the following persons, or by 2 or more of the following persons together:	
(i) the Crown in right of a State;	<input type="checkbox"/>
(ii) a person or body covered by paragraph (b) or (d);	<input type="checkbox"/>
(iii) a person or body covered by either of the above subparagraphs.	<input type="checkbox"/>

4. A Higher Education Institution:

Yes No

5. Other:

Yes No

If you have indicated 'other' please answer the following questions:

Does your organisation have a legal personality i.e. can *the organisation* sue and be sued, sign contracts etc. in its own name?

Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
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If not, is the organisation a branch, agency, or instrumentality, of a legal entity?

Please provide details in the space below.

Organisation Information

Organisation name: (legal entity name)	<input type="text"/>		
ABN:	<input type="text"/>		
Street number and name:	<input type="text"/>		
Town/City:	<input type="text"/>		
State:	<input type="text"/>	Postcode:	<input type="text"/>
Country:	<input type="text"/>		
Postal address: (if different from above)	<input type="text"/>		

CEO or equivalent

Surname:	<input type="text"/>	Preferred first name:	<input type="text"/>
Personal title: (eg Ms/Mr/Dr)	<input type="text"/>	Position title:	<input type="text"/>
Phone number:	<input type="text"/>	Fax number:	<input type="text"/>
Mobile number:	<input type="text"/>	E-mail address:	<input type="text"/>
Street number and name: (if different from org. address)	<input type="text"/>		
Town/City:	<input type="text"/>	State:	<input type="text"/>
Postcode:	<input type="text"/>	Country:	<input type="text"/>
Postal address: (if different)	<input type="text"/>		

Organisation Primary Contact Officer

(The person who will receive all OGTR correspondence)

Surname:	<input type="text"/>	Preferred first name:	<input type="text"/>
Personal title: (eg Ms/Mr/Dr)	<input type="text"/>	Position title:	<input type="text"/>
Phone number:	<input type="text"/>	Fax number:	<input type="text"/>
Mobile number:	<input type="text"/>	E-mail address:	<input type="text"/>
Street number and name: (if different from org. address)	<input type="text"/>		
Town/City:	<input type="text"/>	State:	<input type="text"/>
Postcode:	<input type="text"/>	Country:	<input type="text"/>
Postal address: (if different)	<input type="text"/>		

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 → Go to question 2 No → Go to question 3

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 No

Suspended: Yes No

Surrendered: Yes No

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

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	<input type="checkbox"/>	No	<input type="checkbox"/>
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If yes, please provide details.

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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	<input type="checkbox"/>	No	<input type="checkbox"/>
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If yes, please provide details.

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Question 5 Is there any other information relevant to questions 1 - 4 that may assist the Regulator in making a decision about accreditation?

Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
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If yes, please provide details.

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PART B: Institutional Biosafety Committee (IBC)

Question 6 Does the organisation:

(a) have an established IBC?

Yes → Complete Part C No

(b) have arrangements in place to use an IBC established by another accredited organisation?

Yes → Complete Part D No

If you answered 'yes' to more than one of the above options, please complete all relevant parts.

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 accredit this organisation.

PART C: Established IBC

Access to IBC by organisation / Maintaining a properly constituted IBC

Question 7 How many IBCs has the organisation established?

Please provide the following information, on pages 10 - 13, for each IBC. If more than one IBC has been established, please complete and attach extra copies. Then answer questions 13 – 18 relating to the established IBC(s).

If individual contact details have been previously provided in this application, you need only complete the surname and first name (and any other information necessary to clearly identify the person).

Name of IBC:	<input type="text"/>
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Chair of IBC

Surname:	<input type="text"/>	Preferred first name:	<input type="text"/>
Personal title: (eg Ms/Mr/Dr)	<input type="text"/>	Position title:	<input type="text"/>
Phone number:	<input type="text"/>	Fax number:	<input type="text"/>
Mobile number:	<input type="text"/>	E-mail address:	<input type="text"/>
Street number and name: (if different from org. address)	<input type="text"/>		
Town/City:	<input type="text"/>	State:	<input type="text"/>
Postcode:	<input type="text"/>	Country:	<input type="text"/>
Postal address: (if different)	<input type="text"/>		

Primary Contact for the IBC (if different to Chair)

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

Surname:	<input type="text"/>	Preferred first name:	<input type="text"/>
Personal title: (eg Ms/Mr/Dr)	<input type="text"/>	Position title:	<input type="text"/>
Phone number:	<input type="text"/>	Fax number:	<input type="text"/>
Mobile number:	<input type="text"/>	E-mail address:	<input type="text"/>
Street number and name: (if different from org. address)	<input type="text"/>		
Town/City:	<input type="text"/>	State:	<input type="text"/>
Postcode:	<input type="text"/>	Country:	<input type="text"/>
Postal address: (if different)	<input type="text"/>		

Question 8 Does 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 accredited organisation(s)?

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	<input type="checkbox"/>	No	<input type="checkbox"/>
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If no, please provide reasons.

<input type="text"/>

Question 9 Does the IBC membership 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 why this member is independent to the organisation.

No

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

Indemnification of IBC members

Question 10 Does the organisation have appropriate indemnification for all members of the IBC?

Yes No

If no, please provide explanation.

Question 11 Do all IBC members consider this indemnification to be acceptable?

Yes <input type="checkbox"/>	No <input type="checkbox"/>
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If no, please provide explanation.

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Question 12 Is there any other information relevant to Questions 7 – 12 that may assist the Regulator in making a decision about accreditation?

Yes <input type="checkbox"/>	No <input type="checkbox"/>
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If yes, please provide details.

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PART D: Access to IBC Established by Another Accredited Organisation

Access to IBC by organisation

Question 13 How many IBCs, established by another accredited organisation, will the organisation be using?

- a) Please list the IBCs, their OGTR IBC number, and their parent accredited organisation (ie. the organisation that has established and maintains the IBC).

IBC name	IBC number	Parent accredited organisation (i.e. organisation that established the IBC)

- 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) for each IBC.

Please complete Questions 14 – 18 relating to the IBC(s) established by another accredited organisation.

Question 14 Does 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 accredited organisation(s)?

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.

Question 15 Does the IBC membership 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 why this member is independent to the applicant organisation.

No

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

Indemnification of IBC members

Question 16 Are there appropriate indemnification arrangements for all members of the IBC?

Yes No

Note: When using an IBC established by another accredited organisation it may or may not be necessary for the applicant organisation to arrange the indemnification, depending on the indemnity arrangements made by the IBC's parent organisation. If the parent organisation has indemnification arrangements in place to cover the use of the IBC by the applicant organisation, or if the applicant organisation has agreed to indemnify the IBC members, then tick 'Yes'.

If no, please provide an explanation.

Question 17 Do all IBC members consider this indemnification to be acceptable?

Yes No

If no, please provide explanation.

Question 18 Is there any other information relevant to questions 13 – 17 that may assist the Regulator in making a decision about accreditation?

Yes No

If yes, please provide details.

PART E: Capacity to comply with accreditation conditions

Capacity to comply with accreditation conditions

Question 19 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	<input type="checkbox"/>	No	<input type="checkbox"/>
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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.

Section 3: Declarations

Part A - Declaration of the organisation submitting this application

This declaration must be completed and signed by a person with the authority to sign on behalf of the organisation.

I declare that:

- I am duly authorised to sign this declaration;
- the information supplied on this proforma and any attachment is true and correct; 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* and corresponding state law.

Printed name:		Signature:	
Job title:		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:

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(2) I declare that:

- I am authorised to sign on behalf of:

.....

(other organisation name)

which is accredited by the OGTR (Accreditation number:.....).

- the information provided regarding the IBC named below (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 (3);
- 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.

(3) Name of the IBC to be used:

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Printed name:		Signature:	
Job title:		Date:	