Australian Government
Department of Health and Ageing
Office of the Gene Technology Regulator

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

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.

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.

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

Ethics
The National Framework for the Development of Ethical Principles in Gene Technology was released in 2006 by the Gene Technology Ethics Committee (GTEC) to raise awareness of ethical issues relating to gene technology. Its purpose is to provide the Australian community, and particularly scientists working in gene technology, with a national reference point for ethical considerations. The National Framework provides guidance for considering the ethical implications relevant to all aspects of gene technology.

The OGTR encourages organisations and individuals to refer to this National Framework and to make it available to those involved in the conduct or oversight of gene technology work. The document is available from the OGTR website at: www.ogtr.gov.au

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

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; or
- By facsimile to the Office of The Gene Technology Regulator on (02) 6271 4202; or
- In person at Level 1, Pharmacy Guild House, 15 National Circuit, BARTON, ACT 2600.

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 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.

Yes		No	

B. 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;	
(b) a company in which a controlling interest is held by any one or more of the following together:	
(i) the Commonwealth;	
(ii) a body covered by paragraph (a);	
(iii) a body covered by either of the above subparagraphs.	

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

D. A Higher Education Institution:

Yes		No	

E. 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		No	

If not, is the organisation a branch, agency, or instrumentality, of a legal entity?

Please provide details in the space below.

Part B: Contact Information

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

Organisation Information

Organisation name: (legal entity name)			
ABN:			
Postal Address:			
Postal Locality: (City/Suburb/Location)			
State:		Postcode:	
Country:			

CEO or equivalent

Personal title: (eg Ms/Mr/Dr)		Surname:			
First name:		Preferred first name:			
Phone number:		Mobile:		Fax:	
E-mail Address:					
Position title:					
Organisation (for postal delivery):					
Postal address:					
Postal Locality: (City/Suburb/Location)		State:			
Postcode:		Country:			

Organisation Primary Contact Officer

(The person who will receive all OGTR correspondence)

Personal title: (eg Ms/Mr/Dr)		Surname:			
First name:		Preferred first name:			
Phone number:		Mobile:		Fax:	
E-mail Address:					
Position title:					
Organisation (for postal delivery):					
Postal address:					
Postal Locality: (City/Suburb/Location)		State:			
Postcode:		Country:			

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		Date		No	
Suspended	Yes		Date		No	
Surrendered	Yes		Date		No	
Expired	Yes		Date		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 ☐ No ☐

If yes, please provide details.

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.

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.

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.

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 Primary 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 14)

Question 8

Does the membership of each IBC possess the collective technical 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.

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 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).

Question 10

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

Yes ☐ No ☐

If no, please provide explanation.

Question 11

Do all IBC members consider this indemnification to be acceptable?

Yes ☐ No ☐

If no, please provide explanation.

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.

IBC Contact Details

Name of IBC:	

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).

Chair of IBC

Personal title: (eg Ms/Mr/Dr)		Surname:			
First name:		Preferred first name:			
Phone number:		Mobile:		Fax:	
E-mail Address:					
Position title:					
Organisation (for postal delivery):					
Postal address:					
Postal Locality: (City/Suburb/Location)		State:			
Postcode:		Country:			

Primary Contact for the IBC (if different to Chair)

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

Personal title: (eg Ms/Mr/Dr)		Surname:			
First name:		Preferred first name:			
Phone number:		Mobile:		Fax:	
E-mail Address:					
Position title:					
Organisation (for postal delivery):					
Postal address:					
Postal Locality: (City/Suburb/Location)		State:			
Postcode:		Country:			

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? [ ]

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

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

(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 the 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.

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.

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.

Attachment list

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

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:

.....

(2) Name of the IBC to be used:

……..

(3) **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 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 names 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:		Signature:	
Job title:		Date:	