



Australian Government

Department of Health

Office of the Gene Technology Regulator

Accredited Organisation Annual Report to the Gene Technology Regulator

**Accredited Organisation Name:
(legal entity name)**

Click here to enter text.

Accreditation number:

Click here to enter text.

Reporting Period: 1 July 2019 – 30 June 2020

Is this notification 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

Click here to
enter text.

Click here to
enter text.

General Instructions

Purpose

The purpose of this annual report form is for Accredited Organisations to provide information to the Gene Technology Regulator (the Regulator) to demonstrate that they are meeting obligations and responsibilities under the *Gene Technology Act 2000* (the Act) and corresponding state legislation, the *Gene Technology Regulations 2001* and *Guidelines for Accreditation of Organisations* issued by the Regulator under the Act. Information within an annual report may be subject to monitoring and auditing by staff of the Office of the Gene Technology Regulator (OGTR) or authorised persons appointed by the Regulator under the *Gene Technology Act 2000*. The requirement to complete this form is a condition of accreditation (Condition 10).

Accuracy of information

The information you provide in this report 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).

Personal information

Personal information is collected by the OGTR to enable the Gene Technology Regulator to perform the functions set out in the Gene Technology Act 2000 (the Act). Personal information specified in this form is collected for the purpose of assessing your ongoing suitability to hold accreditation, and compliance with the guidelines and your instrument of accreditation. In addition, these details may be used for the purpose of liaison and consultation about matters relating to the regulation of GMOs in Australia. It 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 APPs can be made.

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

Ethics

The [National Framework of Ethical Principles in Gene Technology 2012](#) (Ethics Framework) has been developed by the Gene Technology Ethics and Community Consultative Committee (GTECCC) to provide a national reference point for promoting ethical conduct in gene technology.

Authorisation

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

Further information

- The OGTR can be contacted by telephone on 1800 181 030 or e-mail at ogtr@health.gov.au. Further information is available on the [OGTR website](#).

Submitting the Annual Report

The completed form can be lodged with the OGTR:

- By e-mail to ogtr.applications@health.gov.au
Note – if sending by e-mail, please either:
 - attach a scanned image of the signed declaration page (Section 3); or
 - if you are the person who is authorised to sign the form, include a statement in your e-mail stating that you are the person duly authorised to sign the declaration.

OR

- By mail to the Office of The Gene Technology Regulator, MDP 54, GPO Box 9848, CANBERRA, ACT, 2601;

OR

- In person at Level 11, Scarborough House, Atlantic Street, WODEN, ACT 2606.

Electronic submission is preferred. Please retain a copy of your completed Annual Report.

Submitting the record of Notifiable Low Risk Dealings (NLRDs)

If any NLRDs are required to be reported to the Regulator, these NLRD records must be submitted via the online NLRD reporting form. Please contact the office of the OGTR to discuss alternative options for submitting NLRDs.

Acknowledgement of receipt

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

Section A

Organisation Details:

Organisation information

Please provide below the current contact details for your organisation.

Contact details	
Name of Accredited Organisation:	<input type="text"/>
Accreditation Number:	<input type="text"/>
ABN (Australian Business Number):	<input type="text"/>
OR ACN (Australian Company Number):	<input type="text"/>
Postal Address:	<input type="text"/>
City/Suburb:	<input type="text"/>
State:	<input type="text"/>
Postcode:	<input type="text"/>

Organisation Name/ Ownership Change

Did the organisation change its name or ownership during the reporting period?

Yes

No

If yes, please provide details below:

Section B

Operations of the Organisation

Suitability

During the reporting period, has the organisation been convicted 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 below:

Click here to enter text.

During the reporting period, has the organisation had revoked, suspended or cancelled, 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?

Yes No

If yes, please provide details below:

Click here to enter text.

Section C

Contact Details of Key Personnel

Please provide below the current contact details for Key Personnel in your organisation.

CEO (or equivalent) Contact Details

Contact details	
Personal title: (eg Ms/Mr/Dr/Prof)	<input type="text" value="Click here to enter text."/>
Given Name:	<input type="text" value="Click here to enter text."/>
Family Name:	<input type="text" value="Click here to enter text."/>
Work Phone Number:	<input type="text" value="Click here to enter text."/>
Mobile:	<input type="text" value="Click here to enter text."/>
E-mail Address:	<input type="text" value="Click here to enter text."/>

If the person assigned as the CEO is also assigned as the Primary Contact, Secondary Contact or IBC Contact then please provide a physical location of the CEO.
(including Building Level Number, Building Name, and Campus if applicable)

In the last twelve months, has either of the following changes occurred which have not yet been notified to the OGTR?

- The CEO has been newly appointed? or
- The postal address of the CEO has changed?

Yes No

If yes, is the CEO's postal address the same as the organisation's postal address entered earlier in this form? (if the same, further contact details do not need to be entered below)

Yes No

If no, please provide details below:

Contact details	
Postal Address:	<input type="text" value="Click here to enter text."/>
City/Suburb:	<input type="text" value="Click here to enter text."/>
State:	<input type="text" value="Click here to enter text."/>
Postcode:	<input type="text" value="Click here to enter text."/>

Organisation Primary Contact Officer for OGTR

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 same as CEO, further contact details do not need to be entered below)

Yes No

If no, please provide details below:

Contact details	
Personal title: (eg Ms/Mr/Dr/Prof)	<input type="text" value="Click here to enter text."/>
Given Name:	<input type="text" value="Click here to enter text."/>
Family Name:	<input type="text" value="Click here to enter text."/>
Work Phone Number:	<input type="text" value="Click here to enter text."/>
Mobile:	<input type="text" value="Click here to enter text."/>
E-mail Address:	<input type="text" value="Click here to enter text."/>

In the last twelve months, has either of the following changes occurred which have not yet been notified to the OGTR?

- The Primary Contact has been newly appointed? or?
- The postal address of the Primary contact has changed?

Yes No

If yes, is the Primary Contact's postal address the same as the organisation's postal address entered earlier in this form? (if the same, further contact details do not need to be entered below)

Yes No

If no, please provide details below:

Contact details	
Postal Address:	<input type="text" value="Click here to enter text."/>
City/Suburb:	<input type="text" value="Click here to enter text."/>
State:	<input type="text" value="Click here to enter text."/>
Postcode:	<input type="text" value="Click here to enter text."/>

Organisation Second Primary Contact Officer for OGTR

(NOTE: this is not mandatory)

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 nominate a secondary contact person?
(If no, contact details do not need to be entered below).

Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
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If yes, is the Secondary Contact the same As CEO Contact?
(if same as CEO, further contact details do not need to be entered below).

Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
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If no, please provide details below:

Contact details	
Personal title: (eg Ms/Mr/Dr/Prof)	<input type="text" value="Click here to enter text."/>
Given Name:	<input type="text" value="Click here to enter text."/>
Family Name:	<input type="text" value="Click here to enter text."/>
Work Phone Number:	<input type="text" value="Click here to enter text."/>
Mobile:	<input type="text" value="Click here to enter text."/>
E-mail Address:	<input type="text" value="Click here to enter text."/>

In the last twelve months, has either of the following changes occurred which have not yet been notified to the OGTR?

- The Secondary Contact has been newly appointed? or
- The postal address of the Secondary Contact has changed?

Yes No

If yes, is the Secondary Contact's postal address the same as the organisation's postal address entered earlier in this form? (if the same, further contact details do not need to be entered below)

Yes No

If no, please provide details below:

Contact details	
Postal Address:	<input type="text" value="Click here to enter text."/>
City/Suburb:	<input type="text" value="Click here to enter text."/>
State:	<input type="text" value="Click here to enter text."/>
Postcode:	<input type="text" value="Click here to enter text."/>

Section D

Access to Institutional Biosafety Committees

Did the organisation continue to have access to an Institutional Biosafety Committee (IBC) during the reporting period?

Yes

No → Please provide a brief explanation below

Click here to enter text.

During the reporting period has the organisation:

- established or used an additional IBC or
- disbanded or ceased to use an IBC?

Yes No

If yes, please provide details below:

Enter name of IBC
Established/commenced
access

Click here to enter text.

And/Or

Enter name of IBC
Disbanded/ceased
access

Click here to enter text.

If the organisation maintains one or more IBC(s) – **complete Section E & F**

If the organisation accesses IBC(s) maintained by another organisation – **complete Section G**

If the organisation maintains one or more IBC(s) AND accesses IBC(s) maintained by another organisation – **complete Section E, F and G**

Section E

Maintaining the IBC(s)

Does the membership of each IBC continue to 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) that use it?

Yes

No → Please provide a brief explanation below

Click here to enter text.

Does the IBC membership include at least one independent member?

Yes

No → Please provide a brief explanation below

Click here to enter text.

Did the members of each IBC established (and maintained) by the organisation continue to have appropriate indemnification and do the IBC members consider their indemnification to be acceptable?

Yes

No → Please provide a brief explanation below

Click here to enter text.

Were minutes of all IBC meetings kept?

Yes

No → Please provide a brief explanation below

N/A → No meetings held during reporting period

Click here to enter text.

Are effective mechanisms in place to address conflicts of interest, for example, a requirement for members to disclose any direct or indirect interest, pecuniary or otherwise, in a matter being considered or about to be considered at, or before, a meeting of the IBC?

Yes

No → Please provide a brief explanation below

Click here to enter text.

Section F

IBC Contact Details

For each existing IBC maintained by the organisation, and any new IBCs established by your organisation during the reporting period, please provide the following contact details.

IBC Name

Click here to enter text.

Chairperson of IBC

Have details for this contact person already been provided earlier in this report.

Yes No

If yes, please indicate which contact already provided above is also appointed the IBC Chairperson. (if already provided, further contact details do not need to be entered below).

	Tick	Confirm Name of contact (e.g. Mr J Smith)
CEO	<input type="checkbox"/>	Click here to enter text.
Primary Contact	<input type="checkbox"/>	Click here to enter text.
Secondary Contact	<input type="checkbox"/>	Click here to enter text.

If no, please provide details below:

	Contact details
Personal title: (eg Ms/Mr/Dr/Prof)	Click here to enter text.
Given Name:	Click here to enter text.
Family Name:	Click here to enter text.
Work Phone Number:	Click here to enter text.
Mobile:	Click here to enter text.
E-mail Address:	Click here to enter text.

In the last twelve months, has either of the following changes occurred which have not yet been notified to the OGTR?

- The IBC Chairperson has been newly appointed? or
- The postal address of the IBC Chairperson has changed?

Yes No

If yes, is the Chairperson’s postal address the same as the organisation’s postal address entered earlier in this form? (if the same, further contact details do not need to be entered below)

Yes No

If no, please provide details below:

Contact details	
Postal Address:	<input type="text"/>
City/Suburb:	<input type="text"/>
State:	<input type="text"/>
Postcode:	<input type="text"/>

IBC Contact Details

This is the person who will be the main point of contact for the OGTR relating to issues that are relevant to IBCs under the Gene Technology legislation.

Have details for this contact person already been provided earlier in this report. (if already provided, further contact details do not need to be entered below).

Yes No

If yes, please indicate which contact already provided above is also appointed the IBC Contact. (if already provided, further contact details do not need to be entered below).

	Tick	Confirm Name of contact (e.g. Mr J Smith)
CEO	<input type="checkbox"/>	<input type="text"/>
Primary Contact	<input type="checkbox"/>	<input type="text"/>
Secondary Contact	<input type="checkbox"/>	<input type="text"/>
IBC Chairperson	<input type="checkbox"/>	<input type="text"/>

If no, please provide details below:

Contact details	
Personal title: (eg Ms/Mr/Dr/Prof)	<input type="text" value="Click here to enter text."/>
Given Name:	<input type="text" value="Click here to enter text."/>
Family Name:	<input type="text" value="Click here to enter text."/>
Work Phone Number:	<input type="text" value="Click here to enter text."/>
Mobile:	<input type="text" value="Click here to enter text."/>
E-mail Address:	<input type="text" value="Click here to enter text."/>

In the last twelve months, has either of the following changes occurred which have not yet been notified to the OGTR?

- The IBC Contact has been newly appointed? or
- The postal address of the IBC Contact has changed?

Yes No

If yes, is the IBC Contact's postal address the same as the organisation's postal address entered earlier in this form?

Yes No

If no, please provide details below:

Contact details	
Postal Address:	<input type="text" value="Click here to enter text."/>
City/Suburb:	<input type="text" value="Click here to enter text."/>
State:	<input type="text" value="Click here to enter text."/>
Postcode:	<input type="text" value="Click here to enter text."/>

Please provide a physical location of the IBC Contact
(including Building Level Number, Building name, and Campus if applicable).

Section G

IBCs Accessed

Please indicate below all IBCs (which are maintained by another organisation) that are accessed by the organisation.

IBC Name

Click here to enter text.
Click here to enter text.
Click here to enter text.
Click here to enter text.
Click here to enter text.

Section H Dealings

Did the organisation maintain records of all current notifiable low risk dealings (NLRDs) and licensed dealings conducted during the reporting period?

Yes	<input type="checkbox"/>	
No	<input type="checkbox"/>	→ Please provide a brief explanation below
N/A	<input type="checkbox"/>	→ No notifiable or licensed dealings conducted

Click here to enter text.

During the reporting period were any of the organisation's dealings assessed by an IBC to be a new NLRD?

Yes	<input type="checkbox"/>	→ Please provide further information below
No	<input type="checkbox"/>	

Click here to enter text.

Copies of the record of IBC assessments of these new NLRDs must be submitted.

Provide the online tracking number/s and the date of each online submission of NLRDs below.

Online Tracking Number	Online Submission Date
Click here to enter text.	Click here to enter a date.

The OGTR expects that all organisations will be using the online form to report NLRDs to the Regulator for the 2019-2020 reporting period. However, if you are experiencing difficulties using the online NLRD reporting form please discuss any possible alternative arrangements for submitting NLRD records with the OGTR.

Other Information

Please provide any other information you wish to add to your report below (not mandatory).

Click here to enter text.

Section I Declaration

This is the declaration of the organisation submitting this annual report.

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

Note: a signature is not required if the completed form is emailed by the authorised person and that person has included a statement in their e-mail stating that they are the person duly authorised to sign the declaration.

I declare that:

- I am duly authorised to sign this declaration;
- To the best of my knowledge, the information supplied on this form and any attachment(s) is not false or misleading; 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:	<input type="text" value="Click here to enter text."/>	Signature:	<input type="text"/>
Job Title:	<input type="text" value="Click here to enter text."/>	Date:	<input type="text" value="Click here to enter a date."/>

Attachment List

Please list all attachments below