



Australian Government

Department of Health and Aged Care  
Office of the Gene Technology Regulator

# Accredited Organisation Annual Report to the Gene Technology Regulator

|  |   |
|--|---|
| <b>Accredited Organisation Name:</b>                                       | <input type="text" value="Enter Organisation Name"/>    |
| <b>ABN:</b>  | <input type="text" value="Enter ABN"/>                  |
| <b>Accreditation number:</b>   | <input type="text" value="Enter Accreditation Number"/> |
| <b>Postal Address:</b><br><i>(must include Suburb, State and Postcode)</i> | <input type="text" value="Enter Postal Address"/>       |

**Reporting Period: 1 July 2023 – 30 June 2024**

This report must not contain any CCI. If you wish to discuss submitting this form with CCI, then contact the OGTR by phone 1800 181 030 or email [ogtr.applications@health.gov.au](mailto:ogtr.applications@health.gov.au).

# General Instructions

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## ***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).

## ***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 Australian Privacy Principles can be made.

## ***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](#).

## ***Authorisation and lodging your report***

The Annual Report 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.

Electronic submission is preferred. However, the completed form can also be submitted by mail to the Office of The Gene Technology Regulator, MDP 54, GPO Box 9848, CANBERRA, ACT, 2601. Please retain a copy of your completed Annual Report.

## ***Further information***

Further information is available on the [OGTR website](#).

The OGTR can be contacted by telephone on 1800 181 030 or e-mail at [ogtr@health.gov.au](mailto:ogtr@health.gov.au).

## ***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](mailto:ogtr.applications@health.gov.au) or telephone 1800 181 030.

## Section 1

### Operations of the Organisation

|  |                              |                             |
|--|------------------------------|-----------------------------|
| Did the organisation change its name or ownership during the reporting period?   | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 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? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 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?  | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| <p>If you answered 'Yes' to any of the above questions, please provide details:</p> <p>Enter Details</p>   |                              |                             |

## Section 2

### Organisation Contact Details

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

#### CEO or equivalent Contact Details

|  |                      |
|--|----------------------|
| Personal title: e.g. Ms/Mr/Dr                                | Select a Title       |
| Given name: (or preferred given name)                        | Enter 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:<br>(must include Suburb, State and Postcode) | Enter postal address |

#### Organisation Primary Contact Officer Details

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.

|  |   |
|--|---|
| Tick if same as CEO  | <input type="checkbox"/><br><i>(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)</i> |
| Personal title: e.g. Ms/Mr/Dr  | Select a Title  |
| Given name: (or preferred given name)  | Enter 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:<br>(must include Suburb, State and Postcode)                           | Enter postal address  |
| Physical location:<br>(including Level/Floor, Building Number/Name and Street Address) | Enter physical location   |

## Organisation Secondary Contact Officer Details

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.

|  |   |
|--|---|
| Tick if same as CEO  | <input type="checkbox"/><br><i>(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)</i> |
| Personal title: e.g. Ms/Mr/Dr:   | Select a Title  |
| Given name (or preferred given name)   | Enter 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:<br>(must include Suburb, State and Postcode)                           | Enter postal address  |
| Physical location:<br>(including Level/Floor, Building Number/Name and Street Address) | Enter physical location   |

## Section 3

### IBC Details

|   |                              |                             |
|---|------------------------------|-----------------------------|
| Did the organisation continue to have access to an Institutional Biosafety Committee (IBC) during the reporting period? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| If no, please provide a brief explanation below:<br>Enter Details   |                              |                             |

During the reporting period has the organisation done either of the following:

|  |                              |                             |
|--|------------------------------|-----------------------------|
| Establish or used an additional IBC?   | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Disbanded or ceased to use an IBC?   | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| If you answered 'Yes' to either of the above questions, please provide details:<br>Enter Details |                              |                             |

If the organisation maintains one or more IBC(s) – **complete Part 1 & 2**

If the organisation accesses IBC(s) maintained by another organisation – **complete Part 3**

If the organisation maintains one or more IBC(s) AND accesses IBC(s) maintained by another organisation – **complete all parts (1-3)**

### Part 1: IBCs Maintained

If the organisation maintains more than one IBC, answer the following questions from the perspective of the group of IBCs as if they were a single IBC.

|  |                              |                             |                              |
|--|------------------------------|-----------------------------|------------------------------|
| Does the membership of the IBC(s) 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?   | <input type="checkbox"/> Yes | <input type="checkbox"/> No |                              |
| 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?  | <input type="checkbox"/> Yes | <input type="checkbox"/> No |                              |
| 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(s)? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |                              |
| <p>If you answered 'No' to any of the above questions, please provide a brief explanation:</p> <p>Enter Details</p>  |                              |                             |                              |
| Does the IBC membership include at least one independent member?   | <input type="checkbox"/> Yes | <input type="checkbox"/> No |                              |
| <p>If you answered 'No' to the above question, please provide reasons below.</p> <p>Enter Details</p> <p>If you answered 'Yes' to the above question, please describe how the member is independent.</p> <p>Enter Details</p>  |                              |                             |                              |
| Were minutes of all IBC meetings kept?   | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A |

## Part 2: 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.

If your organisation uses multiple IBCs, please copy and complete both contact tables for each 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.

### IBC Chairperson

|  |  |
|--|--|
| IBC Name   | Enter IBC Name   |
| Tick if contact details have already been provided                                     | <input type="checkbox"/> CEO (enter physical location below)<br><input type="checkbox"/> Primary Contact<br><input type="checkbox"/> Secondary Contact |
| Personal title: e.g. Ms/Mr/Dr  | Select a Title   |
| Given name: (or preferred given name)  | Enter 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:<br>(must include Suburb, State and Postcode)                           | Enter postal address   |
| Physical location:<br>(including Level/Floor, Building Number/Name and Street Address) | Enter physical location  |



## IBC Contact

|  |  |
|--|--|
| IBC Name   | Enter IBC Name   |
| Tick if contact details have already been provided                                     | <input type="checkbox"/> Chairperson (enter physical location below)<br><input type="checkbox"/> CEO (enter physical location below)<br><input type="checkbox"/> Primary Contact<br><input type="checkbox"/> Secondary Contact |
| Personal title: e.g. Ms/Mr/Dr  | Select a Title   |
| Given name: (or preferred given name)  | Enter 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:<br>(must include Suburb, State and Postcode)                           | Enter postal address   |
| Physical location:<br>(including Level/Floor, Building Number/Name and Street Address) | Enter physical location  |

## Part 3: IBCs Accessed

Please list below all IBCs maintained by another organisation that are accessed by the organisation.

| IBC name                         |
|----------------------------------|
| Click or tap here to enter text. |

(If there is more than one IBC, please add additional rows.)

## Section 4 Dealings

|  |                              |                             |  |
|--|------------------------------|-----------------------------|--|
| Did the organisation maintain records of all current notifiable low risk dealings (NLRDs) and licensed dealings conducted during the reporting period?   | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A<br><i>(no dealings conducted)</i> |
| If no, please provide a brief explanation below.<br>Enter Details  |                              |                             |  |
| During the reporting period were any of the organisation's dealings assessed by an IBC to be a new NLRD?   | <input type="checkbox"/> Yes | <input type="checkbox"/> No |  |
| If yes, have all the NLRDs assess during the reporting period been reported to the OGTR?<br><i>Note: The NLRD reporting form is available in the OGTR Online Services Portal or via a downloadable form on the OGTR website. Please refer to the <a href="#">OGTR website</a> for details.</i> | <input type="checkbox"/> Yes | <input type="checkbox"/> No |  |
| If no, to the question directly above, please provide a brief explanation below.<br>Enter Details  |                              |                             |  |

## Section 5 Other Information

|   |
|---|
| Please provide any other information you wish to add to your report below <i>(not mandatory)</i> .<br>Enter Details |
|---|

## Section 6 Declaration

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: | Enter name                    |
| Signature:    |                               |
| Date:         | Click or tap to enter a date. |