Application for a licence

To conduct a human clinical trial of a genetically modified organism

Project title: e.g., Clinical trial of GM <parent organism> for treatment of <condition>. Note: a list of licence applications and issued licences is published on the OGTR website. A short title suitable for publication is suggested. Do not include Confidential Commercial Information (CCI) in the title.	Enter title
Applicant organisation name:	Enter name
Applicant organisation accreditation number: (if accredited by the Gene Technology Regulator) Apply for accreditation.	Enter number
Requested duration of the licence Note: This should be based on the intended duration of the clinical trial, with reasonable allowance for delays. DNIR licences are generally issued for a maximum of five years.	

Protecting Confidential Commercial Information (CCI)

If you wish to protect any information on this form or in any attached documents as CCI under the *Gene Technology Act 2000* (the Act), you may need to submit an Application for Declaration that specified information is CCI. For additional information, please see OGTR fact sheet How we treat Confidential Commercial Information.

The application for a CCI declaration should be submitted with the licence application

Before applying for a CCI declaration, we encourage you to contact the OGTR to discuss whether the information you seek to protect is needed to assess your application. If we do not require the information for the assessment, then we do not need to know that information.

Does this application contain CCI? ☐ Yes ☐ No

If yes, please select the situation that applies to you:

☐ None of the CCI is covered by previous CCI application(s) and you are submitting an Application for Declaration that specified information is CCI with this licence application.

☐ All the CCI is covered by previous Applications for Declaration that specified information is CCI and there is no need to make a new application. Provide the previous application number(s) here:

Enter CCI application number(s)

☐ Some but not all of the CCI contained in this application is covered by previous Applications for Declaration that specified information is CCI. You are submitting a new application with this licence application to protect new CCI. Provide the previous CCI application number(s) here:

Enter CCI application number(s)

Time taken to complete this form: Enter hours Enter minutes

Information for applicants

Contact us

We encourage prospective applicants to contact the OGTR before submitting a written application to discuss information requirements or ask any questions about this form. You can also contact us if you would like feedback on a draft application.

You may call (1800 181 030) or email us (ogtr.cdes@health.gov.au).

Further information about regulation of clinical trials is also available in the document *Guidance for conducting human clinical trials with GMOs - Requirements under the* Gene Technology Act 2000, available on the OGTR website.

What is this application form for?

This form is for applying to the Gene Technology Regulator (the Regulator) for a licence to conduct a human clinical trial of a genetically modified organism (GMO). The term 'human clinical trial' refers to a clinical study involving the introduction of a genetically modified organism (GMO) into human beings. Regulatory requirements for human clinical trials depend on the properties of the GMO, with most trials requiring a licence. Only a few types of human clinical trial do **not** require a licence, e.g., those involving the introduction of human somatic cells where the genetic modification occurred outside of the trial participant and meets several other requirements.

Types of licence

There are two types of licence, authorising either:

- dealings involving intentional release (DIR) into the environment; or
- dealings **not** involving intentional release (DNIR)

The document *Guidance for conducting human clinical trials with GMOs - Requirements under the* Gene Technology Act 2000 provides more information about how these apply to clinical trials involving GMOs. You may use this application form to apply for either a DIR or a DNIR licence. The first question prompts you to select the type of application appropriate for your clinical trial (see Part 1). If you are uncertain as to the appropriate category, please discuss with the OGTR before submitting the application.

Note that, under the Act, processing requirements and timeframes for DNIR and DIR licence applications are different, with a longer timeframe for DIR assessments as outlined below.

How should you fill out this form?

- We recommend that you read through all the questions, including the guidance text, before filling out the form. Please refer to any sample answers provided. This will help you focus your responses on the information we need.
- You must answer each question unless instructed otherwise.
- Provide written responses in this form rather than as separate attachments. However, you may submit multiple or large illustrations as attachments if preferred. You may also choose to provide clinical trial documents in response to questions in Part 14 (e.g., the clinical trial protocol, pharmacy manual etc). Identify the relevant sections of these documents in your answers.
- If the application involves GMOs based on more than one parent organism, you will need to duplicate Part 10 (The genetic modification(s)) and Part 20 (Additional information about the parent organism) for any parent organisms not previously assessed by the OGTR, and describe each GMO and parent organism separately.
- If you wish to provide details of more than one clinical trial, you may enter this information in the relevant sections of Part 13, or duplicate Part 13 and describe each trial separately.
- Ensure you answer each relevant question in sufficient detail. Not providing required information could delay a decision, or the Regulator may cease to consider your application (section 43 of the Act).
- Ensure you answer each question to the best of your knowledge. Deliberately providing false or misleading information is a punishable offence (section 192 of the Act).

- Ensure you include adequate supporting material in your responses. Scientific information should be relevant, comprehensive and supported by data and references. If you cite unpublished information, we may ask you to provide electronic copies during the assessment process.
- Do not repeat information. If necessary, refer to your answers to other questions.

What is the IBC review process?

To ensure that the information included is complete, licence applications must be reviewed and endorsed by an Institutional Biosafety Committee (IBC) before being submitted to the Regulator (see Part 6). The IBC must have appropriate collective technical and scientific expertise to review the application.

How can you submit this form?

Once you have obtained the relevant signatures (Part 7 of this form):

- Send the completed application form electronically **in a searchable format** to: ogtr.applications@health.gov.au (preferred); or
- Mail the application files on a USB stick to: Office of the Gene Technology Regulator, MDP 54, GPO Box 9848, Canberra, ACT, 2601

Applications containing sensitive information such as CCI or confidential details about applicant suitability can be transmitted securely using the Australian Government's Health Data Portal or the secure email service used by the Department of Health and Aged Care. For assistance with establishing access to either of these, contact ogtr.applications@health.gov.au. Applications containing CCI may also be submitted on a USB stick via Express Post.

If you choose to provide sensitive information by standard email, be aware that this is transmitted via an unclassified internet connection and will not be protected in the process. Within a reasonable time of receipt of the application, staff in the OGTR will securely store the sensitive information.

What is the application fee?

There is currently no application fee.

What will happen after you have submitted the application?

We will acknowledge receipt of the application by email. Our office will then conduct an initial screening of the application to ascertain completeness for the purpose of assessment. If the application is sufficiently complete to accept and begin evaluation, we will assign it an OGTR reference number and send the reference number by email. Cite this reference number whenever you contact us regarding the application.

Contact us (ogtr.applications@health.gov.au) if we have not acknowledged receipt of the application within two weeks of submission.

How will we use the information provided in this form?

We will use the information you provide to prepare a Risk Assessment and Risk Management Plan (RARMP) in relation to the proposed clinical trial. The purpose of the RARMP is to identify risks to the health and safety of people and to the environment, and to address the management of those risks. The Regulator's decision to issue a licence or not is based upon the RARMP.

Our assessment focuses on risks to ***people other than trial participants*** – e.g., clinical trial staff handling the GMO; carers, household members and members of the community who may be exposed to the GMO via trial participants; and to ***animals***, such as pets, livestock and native wildlife. This is different to the Human Research Ethics Committee (HREC) assessment, which focuses on safety of trial participants. Both assessments rely on data you provide about biological safety in humans and animals.

As part of the Regulator's obligations under the legislation, information in this application may be provided to relevant Commonwealth authorities or agencies, state and territory governments, local councils and to the Gene Technology Technical Advisory Committee. Information may also be released to the public (see below).

What happens if we need more information during assessment of your application?

We may ask you for additional information in relation to your application and set a date by which to provide it.

- We may pause the assessment of your application until we receive this information.

- The Regulator may cease to consider your application if you do not provide the requested information on time.

What information will be publicly released?

- For **DNIR licence applications**, the project title and a brief summary of the project (1-2 sentences) will be published on the OGTR website.
- For **DIR licence applications**, the Regulator must provide a copy of a submitted DIR application to anyone requesting it (section 54 of the Act). This includes information about applicant suitability provided in Part 5.3-5.6 and any clinical trial documents you choose to provide as part of the application. In addition, both the RARMP and the licence, will be consulted on and published on the OGTR website.
- For both DNIR and DIR licences, certain information may be released to the public in response to a request to inspect the GMO record (section 139 of the Act).

What information will not be publicly released?

Regardless of the above:

- Information declared or under consideration as Confidential Commercial Information (CCI) by the Regulator cannot be disclosed (section 187 of the Act), is not included in the GMO Record (section 138 of the Act) and is exempt from disclosure under the *Freedom of Information Act 1988;*
- Information in the application about relevant convictions (section 58 of the Act) cannot be disclosed; and
- Personal information will only be disclosed in accordance with the *Privacy Act 1988*.

How long will it take the Regulator to decide whether or not to issue a licence?

- If your application is eligible for a **DNIR licence**, the Regulator must make a decision within 90 working days.
- If your application requires a **DIR licence** and qualifies as a limited and controlled release, the Regulator must make a decision within 150 working days, or 170 working days if a significant risk is identified.

Weekends and ACT public holidays are excluded from these decision-making timeframes, as are any days on which the Regulator cannot proceed with the decision-making process while awaiting requested information.

Table of Contents

1. Type of licence required

Please refer to *Requirements under the Gene Technology Act 2000 for clinical trials in humans involving GMOs – Guidance for clinical trial sponsors*, for information about types of licence. If the clinical trial **does not** involve the intentional release of the GMO into the environment, a DNIR licence is appropriate. If the clinical trial **does** involve the intentional release of the GMO into the environment, a DIR licence is required.

1.1. Will any of the proposed dealings involve the intentional release of a GMO into the environment?

☐ Yes – this application is for a DIR licence

☐ No – this application is for a DNIR licence

Note 1: Information provided in Parts 9-13 and Part 20 of the application should support your response. We acknowledge that this distinction may not be clear for many clinical trials. If you are uncertain as to the appropriate category, we encourage you to seek advice from the OGTR before submitting this form. Ultimately, the Regulator will decide whether to treat your application as a DNIR or DIR licence application.

Note 2: Under the Act, DIR and DNIR licence applications are processed differently.

Personal Information

Personal information is collected by the OGTR to enable the Regulator to perform the functions set out in the Act. Personal information requested 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 on collection and handling of personal 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.

2. Contact Person for the Application

The contact person must be authorised to act on the applicant's behalf in relation to this application. OGTR staff may contact this person during the assessment of the licence application to request additional information. The authorised person identified here may also be the person nominated in Part 3.

Title (e.g., Prof/Dr/Ms/Mr):	Enter title
Surname:	Enter name
First name:	Enter first name
Preferred first name if different:	Enter first name
Phone number:	Enter phone number
Mobile number:	Enter mobile number
Email address:	Enter email address
Job title:	Enter job title
Organisation:	Enter organisation
Street number and name:	Enter street number and name
Town/city/locality:	Enter town/city
State/territory:	Enter state/territory
Postcode:	Enter postcode
Country:	Enter country

3. Technical Contact for the Application

OGTR staff may seek additional information from the technical contact during assessment of the application. This person should be familiar with the application and have suitable technical knowledge and skills to answer questions about how the proposed clinical trial will be conducted.

Consider whether multiple persons with appropriate technical knowledge and skills could be listed for this purpose. If you wish to list more than one technical contact, duplicate this page for each person, providing details of their knowledge and skills relevant to the application. This will allow OGTR staff to contact the most appropriate person if further information is needed.

Is the person nominated in this Part the same as the authorised person for the application in Part 2?

☐ Yes

☐ No

If yes, complete the last row only. If no, complete all rows.

Title (e.g., Prof/Dr/Ms/Mr):	Enter title
Surname:	Enter surname
First name:	Enter first name
Preferred first name, if different:	Enter preferred first name
Phone number:	Enter phone number
Mobile number:	Enter mobile number
Email address:	Enter email address
Job title:	Enter job title
Organisation:	Enter organisation
Street number and name:	Enter street number and name
Town/city/locality:	Enter town/city
State/territory:	Enter state/territory
Postcode:	Enter postcode
Country:	Enter country
Relevant qualifications and skills:	Enter relevant qualifications and skills

4. Applicant Type

This information is required to establish whether your proposed dealings are subject to the *Commonwealth Gene Technology Act 2000* or to State[1] legislation. It is advisable to check with your organisation's legal area or executive before completing this Part.

4.1. This application is being made by:

☐ a natural person (proceed to Part 5)

☐ an organisation

4.2. Information about the type of applicant organisation

If the application is by an organisation, indicate below which of the following 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, is the organisation a:

☐ Higher Education Institution

☐ Hospital

☐ Research Institute or similar

☐ 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

☐ 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

☐ Corporation which is none of the above. Please provide details.

Enter text

b. For an organisation which is NOT a constitutional corporation, is the organisation a:

☐ Higher Education Institution

☐ Hospital

☐ Research Institute or similar

☐ Commonwealth Department

☐ State Government Department

☐ Organisation which is none of the above. Please provide details.

Enter text

[1] 'State' includes the Australian Capital Territory and the Northern Territory (Section 10 of the Act).

5. Suitability of the Applicant

The Act requires the Regulator to be satisfied that an applicant is suitable to hold a licence before issuing a licence. Information provided in this Part will assist the Regulator in making this determination.

5.1. Has the applicant been convicted of an offence against a law of the Commonwealth, a State[2] or a foreign country which relates to the health and safety of people or the environment where the offence was committed within a period of ten years immediately before the making of the application for this licence and which was punishable on conviction by a fine of $5000 or more, or by a term of imprisonment of one year or more?

☐ Yes

☐ No

If yes, provide details of:

- the Act the offence was committed under
- the date the offence was committed
- the date of the conviction
- the penalty which was imposed and
- why the Regulator should still consider the applicant suitable to hold a licence.

Enter text

5.2. If the applicant answered yes to the preceding question and is a body corporate:

a. Was any person who is currently a director of the applicant also a director of the applicant at the time that the offence was committed?

☐ Yes – if so, please provide director's name.

☐ No

Enter text

b. Was any person who is currently an officer or shareholder of the applicant, in a position to influence the management of the applicant, also such an officer or shareholder at the time that the offence was committed?

☐ Yes – if so, please provide details.

☐ No

Enter text

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

☐ Yes – if so, please provide details.

☐ No

Enter text

[2] 'State' includes the Australian Capital Territory and the Northern Territory (Section 10 of the Act).

5.4. To the best of the applicant's knowledge, will the applicant be financially viable for the proposed duration of the licence?

☐ Yes

☐ No

If no, justify why the Regulator should consider the applicant suitable to hold a licence.

Enter text

5.5. What is the date of the applicant's latest financial statement?

Select date

5.6. Attach copies of the applicant's latest financial statement and either the audit findings or a statement from a director of the company (or a person otherwise authorised to make the statement) that the financial statement provided presents a true and fair view, in all material aspects, of the affairs of the applicant for the period covered by the statement.

The Regulator will not consider an application unless it is accompanied by the required financial information. If available, an electronic copy of the financial statement can be provided, e.g., by providing the URL for a statement that is available on the internet.

Note: If an applicant organisation is fully supported by a different parent company, we may also request a financial statement for the parent company.

Enter URLs or attachment numbers

5.7. What is the expected date of the applicant's next financial statement?

If the applicant's next financial statement is prepared prior to the Regulator reaching a decision on this application, a copy of the financial statement must be sent to the OGTR as soon as it is available.

Select date

5.8. Is there any other information relevant to the above questions that may assist the Regulator in making a decision about the suitability of the applicant for a licence?

☐ Yes – if so, please provide details.

☐ No

Enter text

6. Supporting Information from the Institutional Biosafety Committee (IBC)

This part must be completed by the IBC responsible for endorsing the licence application. The IBC should check the application for completeness, assess the adequacy of the answers provided and if needed, provide advice to the applicant and review a revised form. **The application should not be submitted until the IBC considers it satisfactorily completed.**

Name of IBC	Enter name
Date of **final** IBC evaluation of this application	Select date

Name of IBC contact person	Enter name
Phone number of IBC contact person	Enter phone no.
Email address of IBC contact person	Enter email

6.1. When considering the information contained in this application, was the IBC constituted in accordance with the relevant provisions of the Regulator's *Guidelines for the Accreditation of Organisations*?

☐ Yes

☐ No

Provide more detail, if needed.

Enter text

6.2. Please confirm that the IBC has reviewed the application in full

☐ Yes – Application reviewed in full

Provide more detail, if needed.

Enter text

6.3. Does the IBC consider that all relevant questions have been answered satisfactorily?

☐ Yes – all relevant questions are answered satisfactorily

Provide more detail, if needed.

Note: If the application is not satisfactorily completed, it should be returned to the applicant for revision with a request that it be resubmitted to the IBC for review once the issues have been fully addressed.

Enter text

7. Declarations

Parts 6 and 7 must be completed after the applicant has completed all other Parts in this application.

I DECLARE THAT:

- I am duly authorised to sign this declaration; and
- to the best of my knowledge, the information supplied on this form and any attachments 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.

CEO (or Delegate with Authority to Sign) of the Applicant Organisation

Print name:	Print name
Signature:	.....
Job title:	Enter job title
Date:	Select date

Contact Person for the Application as nominated in Part 2 (if different from the CEO)

Print name:	Print name
Signature:	.....
Job title:	Enter job title
Date:	Select date

Technical Contact (if different from the Contact person)

Print name:	Print name
Signature:	……
Job title:	Enter job title
Date:	Select date

IBC Chair

Print name:	Print name
Signature:	……
Job title:	Enter job title
Date:	Select date

8. Summary information about the application

8.1. Proposed dates of commencement and completion

Anticipated commencement date: Enter text

Anticipated completion date: Enter text

8.2. Purpose of the clinical trial

Please describe the purpose of the study in one or two sentences of plain English. This description may be used on the OGTR website so should not contain confidential information.

Sample response: To test the safety and efficacy of GM <parent organism> in adult patients with <medical condition>.

Enter text

8.3. Details of the scientific background of the proposed clinical trial

Please limit your answer to about one page.

Enter text

8.4. Proposed dealing(s) with the GMO(s)

Please select from the following list all activities that describe your proposed work with the GMO(s):

- ☐ Make, develop, produce or manufacture the GMO
- ☐ Import the GMO
- ☐ Breed the GMO
- ☐ Propagate the GMO
- ☐ Grow, raise or culture the GMO
- ☐ Conduct experiments with the GMO *(note that clinical trials are experiments)*
- ☐ Use the GMO in the course of manufacture of a thing that is not the GMO
- ☐ Transport the GMO
- ☐ Dispose of the GMO

Note: These include possession, supply or use of the GMO for the purposes of, or in the course of the listed dealings.

8.5. Briefly describe where the GMO(s) will be sourced from

E.g., will the GMO(s) be imported from overseas, supplied by another Australian organisation, or manufactured in Australia as a Notifiable Low Risk Dealing or under this licence (if issued)?

Enter text

8.6. Identity of clinical trial sites and other organisations involved in the proposed clinical trial

If known, identify the clinical trial sites and any other organisations, such as those providing storage and distribution, dispensing, analytical or waste disposal services, that you expect to be involved in the trial.

If sites/organisations have not yet been identified, indicate the types of site or organisation that you expect to engage.

Enter text

8.7. Rationale for choice of clinical trial sites and other organisations

Outline the reasons for choosing these clinical trial sites and facilities that are relevant to their capacity to work safely with GMOs. If sites have not yet been identified, what relevant criteria will be applied to their selection?

Enter text

8.8. DIR applications only: limits and controls on the proposed release of the GMO(s)

Section 50A of the Act requires that an application for a Limited and Controlled DIR licence propose:

- **Limits** on the proposed release of the GMO; and
- **Controls** to restrict the dissemination or persistence of the GMO and its genetic material in the environment.

List the limits on the proposed release of the GMO(s)

What factors in your proposal would limit the release of the GMO(s)? These could include:

- the number and specific locations of clinical trial sites;
- the maximum number of trial participants to be enrolled;
- relevant inclusion and exclusion criteria;
- the proposed duration of the clinical trial; and
- restrictions on persons who may conduct dealings with the GMO(s).

Note: Brief dot points are sufficient. More detail about these factors is requested elsewhere in this form.

Enter text

List the controls on the proposed release of the GMO(s)

Within the context of the limits listed above, list proposed controls that would restrict the spread and persistence of the GMO(s) in the environment. These could include:

- the types of site and geographic locations where the clinical trial will take place;
- methods for disposal of the GMO(s);
- adherence to guidelines issued by the Regulator;
- measures to minimise exposure of people other than trial participants (e.g., clinical trial staff and other people whom participants may come into contact with) to the GMO(s);
- measures to minimise exposure of susceptible animals (e.g., household pets, livestock and wildlife) to the GMO(s).

Note: Brief dot points are sufficient. More detail about these factors is requested elsewhere in this form.

Enter text

9. The parent organism

The 'parent organism' is the organism that has been genetically modified to create the GMO. For viral vectors, the parent organism is the virus from which the vector genome was derived. For synthesised DNA, the parent organism is the organism on which the DNA sequence was based. If you are unsure what the parent organism is, please contact the OGTR.

Information about the parent organism forms a baseline against which the GMO is assessed to determine whether the modifications introduced by gene technology increase the level of risk or introduce additional risks compared to the parent organism.

9.1. What is the common name of the parent organism(s)?

Include common names that are widely used in Australia and elsewhere.

Enter text

9.2. What is the scientific name of the parent organism(s)?

Please ensure the scientific name you provide is taxonomically correct, and in the form *Genus species* (where applicable). If relevant, include the specific strain and/or serotype to be used.

Enter text

9.3. Has the OGTR assessed all parent organisms previously?

- ☐ Yes
- ☐ No

Refer to the list of previously assessed organisms below. For all previously assessed parent organisms, please check the relevant boxes. **For any parent organism(s) not listed, please complete Part 20.**

Note: This list will be expanded as the OGTR assesses GMOs based on additional parent organisms.

Viruses

- ☐ *Adeno-associated virus*
- ☐ *Adenovirus* (human)
- ☐ *Adenovirus* (chimpanzee)
- ☐ *Chikungunya virus*
- ☐ *Cytomegalovirus* (human)
- ☐ *Dengue virus*
- ☐ *Getah virus*
- ☐ *Hepatitis C virus*
- ☐ *Herpes simplex virus-1*
- ☐ *Human immunodeficiency virus-1*
- ☐ *Maraba virus*
- ☐ *Measles morbillivirus* (Measles virus)
- ☐ Modified vaccinia Ankara (MVA)
- ☐ Mycobacteriophage BPs
- ☐ *Severe acute respiratory syndrome coronavirus-2* (SARS-CoV-2)

☐ *Vaccinia virus*

☐ *Vesicular stomatitis virus*

Bacteria

☐ *Bifidobacterium longum*

☐ *Helicobacter pylori*

☐ *Mycobacterium bovis*, strain Bacille Calmette Guerin (BCG)

☐ *Escherichia coli*

Protozoa

☐ *Plasmodium falciparum*

10. The genetic modification(s)

Questions in this part will help you provide all relevant information about the genetic modifications introduced into the parent organism(s).

If there is more than one parent organism, please duplicate this section and describe the genetic modifications for each one.

10.1. Provide details of genetic modifications to the genome of the parent organism, the functions of genes or genetic elements that have been modified, introduced or deleted, and the effects of the changes on phenotype of the organism

In your response, consider:

- point mutations;
- genes/expression cassettes/other genetic material introduced into the parent organism;
- genes or other genetic material deleted from the genome of parent organism;
- introduced genetic material that is intended to knock out or modify the expression/function of an endogenous gene; and
- any other type of genetic modification.

Where genetic material has been introduced into the parent organism, provide details of genes and associated genetic elements e.g., promoter/enhancer elements, introns, internal ribosome entry sequences, polyadenylation sequences, visual markers such as GFP, antibiotic resistance genes and any epitope/protein tags. Include the common and scientific name of the source organism and the function of the genes/sequences in the source organism.

If introduced genetic material is involved in the production of a known toxin, or has been implicated in a toxic effect, include relevant details and toxicity data.

For viral vectors, describe how the genome of the parent virus has been modified to generate the viral vector genome. Note that details of genes provided *in trans* during packaging are requested in Part 10.3.

Enter text

10.2. Describe vectors and/or other methods used to modify the parent organism

For commercially available vectors, provide the name of the supplier and relevant documentation (or links to documentation) describing the product. Please describe novel vectors or other methods of transfer, including references and/or vector maps to support your response.

Enter text

10.3. For GMOs that are viruses or viral vectors, provide details of the following:

a) any genes supplied *in trans* during production (e.g., capsid, envelope or accessory genes) that are not part of the viral vector genome, plasmids carrying the supplied genes, and packaging cells used to generate viral vector particles

Enter text

b) any impact on cell types transduced or infected due to altered envelope or capsid proteins

Enter text

c) presence or absence of a Self INactivating (SIN) mutation (if the GMO is a lentivirus or gamma retrovirus-based viral vector)

Enter text

d) the ability of the GM virus or viral vector to replicate in human cells and in cells of other susceptible organisms. If the GMO is intended to replicate preferentially in cancer cells, include data (*in vitro* and/or *in vivo*) showing the extent of replication in non-cancerous cells.

Enter text

e) if the GM virus or viral vector is replication incompetent:

- **Explain the basis for replication incompetence**
- **Describe its potential for re-acquiring the ability to replicate during the manufacturing process**
- **Will *each batch* of the GMO be tested for replication competence before release?**

Enter text

f) the potential for *in vivo* complementation of any deleted/disrupted genes or for recombination with wild-type viruses

Consider in your response the potential for the GMO to come into contact with the parent organism or other compatible viral species, taking into account the route of administration, subsequent biodistribution of the GMO, the anatomical locations where compatible viral species may be found, and prevalence of compatible viral species in the target population.

Enter text

11. Preclinical and clinical data

Questions in this section should be answered using information obtained in preclinical and clinical studies involving the same GMO(s) (where available) or very similar GMO(s) (e.g., the same viral vector carrying a different transgene).

11.1. Provide details of any previous approvals related to the GMO, in Australia and internationally

Enter text

11.2. Summarise any adverse effects of administering the GMO(s) to laboratory animals in studies undertaken to date with the GMO(s) or with similar GMO(s)

This question seeks information regarding potential harms related to exposure to the GMO(s). Include:

- the number of studies previously undertaken, and the number and species of animals treated with the same or similar GMO(s); and
- a summary of all adverse events reported and their frequency.

Enter text

11.3. Summarise any adverse effects of administering the GMO(s) to humans in studies undertaken to date with the GMO(s) or with similar GMO(s)

This question seeks information about potential harms related to exposure to the GMO(s). Include:

- the number of studies undertaken, and the number of humans treated with the same or similar GMO(s); and
- a summary of all reported adverse events and their frequency.

Enter text

11.4. Provide information on the ability of the GMO(s) to multiply in trial participants

Include evidence to support any anticipated tissue specificity, e.g., due to selective replication in cancer cells.

Enter text

11.5. Provide information on the pharmacokinetics and biodistribution of the GMO(s) in animal and human hosts following administration by the route(s) proposed for this trial

Include information about the systemic concentration of the GMO(s) in blood, plasma or serum, and its presence in organs and tissues from which biological samples will be collected at times relevant to sample collection and trial participants returning home from the clinical trial site.

Enter text

11.6. Provide information on the potential for the GMO(s) to be shed from trial participants, e.g., via secretions, excreta or lesions related to the GMO(s), during or after the trial

This question seeks information about shedding of viable GMOs, not degradation products or other non-viable material. Include information on:

- methods used for assessment of shedding;
- shedding studies conducted on the GMO(s) or similar GMO(s);
- observed shedding pathways, e.g., via skin lesions resulting from treatment with the GMO, semen, vaginal secretions, saliva, nasal secretions, tears, urine and faeces; and
- the observed duration of shedding via different routes.

Note: Your response to this question should support the type of licence (DIR or DNIR) selected in Part 1 of this form.

Enter text

12. Dissemination of the GMO(s) into the environment

12.1. Describe the potential for a person other than a trial participant to be exposed to the GMO(s) in a manner that could lead to infection or colonisation

Persons may be exposed, for example, when handling the GMO(s) during dose preparation and administration of the GMO, following administration if the procedure allows the GMO to disseminate within the clinical trial site, if there is a spill of the GMO(s) during transport or storage, or if the GMO is shed by trial participants or transmitted by insect vectors. Include, but do not limit to, information on:

- the potential for dissemination to people involved in conducting the trial, other people at the clinical trial site, close contacts of trial participants, and the general population; and
- if such potential exists, the likely mechanism (e.g., occupational exposure, close personal contact, sexual contact, insect vector, etc.) and frequency of such spread.

Note: Your response to this question should support the type of licence (DIR or DNIR) selected in Part 1 of this form.

Enter text

12.2. Describe potential harms to persons other than trial participants exposed to the GMO(s)

Exposed persons may include healthcare professionals, carers or family members of participants, external service providers such as couriers and waste contractors, and in some cases, the general public. These groups may include vulnerable persons such as immunocompromised or elderly people, pregnant women, foetuses and infants who may be particularly susceptible to the GMO.

Enter text

12.3. Describe the potential for animals to be exposed to the GMO(s) in a manner that could lead to infection or colonisation

Exposure of household pets, livestock or wild animals may occur if the GMO(s) are shed by trial participants or transmitted by insect vectors, spilled during transport, or disposed of without adequate decontamination.

Enter text

12.4. Describe potential harms to animals exposed to the GMO(s)

Animals susceptible to disease caused by the parent organism may be adversely impacted by the GMO.

Enter text

12.5. Describe the potential for genomic integration

Consider the potential for genetic material from the GMO(s) to integrate, in whole or in part, into the genome of any cells within an infected or colonised person or animal.

Enter text

13. Details of the proposed clinical trial

This section aims to gather information about how the proposed clinical trial would be conducted.

13.1. Outline the clinical trial protocol

Briefly summarise the clinical trial methodology, including the number and timing of GMO doses administered to each trial participant. Details about the schedule of visits are requested in Part 13.6.

Enter text

13.2. Details about trial participants

Include:

- the estimated maximum number of participants to be treated within Australia as part of the clinical trial over the period of the licence;
- all inclusion and exclusion criteria for participants in the trial; and
- details of any supplementary treatments to be given in conjunction with the GMO(s) (e.g. immunosuppressive treatments).

Enter text

13.3. Details of the GMO as supplied

Describe the form of the GMO at the commencement of activities to be authorised by this licence, e.g., at the time of import into Australia, or as supplied by an Australian manufacturer to clinical trial sites. Include:

- the type of container and seal;
- the physical form of the GMO(s) (e.g., lyophilised powder, frozen liquid);
- the concentration of the GMO; and
- the volume and/or quantity per individual container.

Enter text

13.4. Preparation of the GMO for administration to trial participants

Describe:

- persons or class of persons who will prepare the product for administration (e.g., pharmacists, medical scientists; laboratory technicians);
- training and experience of persons preparing the GMO relevant to minimising their likelihood of exposure, e.g., training and experience with Sharps Injury Prevention;
- the step-by-step process to be followed to prepare the product for administration. Include dilution steps, materials used (e.g., pipettes, syringes, needles, IV bags) and details of any steps where sharps handling is required;
- any aerosol containment equipment that will be used (e.g., biological safety cabinet or pharmaceutical isolator);
- specific personal protection equipment (PPE) to be used; and
- any measures in place to promote safe handling of sharps (e.g., use of safety-engineered sharps devices, specific procedures to manage removal or recapping of needles if the protocol requires this).

Enter text

13.5. Administration of the GMO(s) to trial participants

Include:

- the route of administration;
- the concentration and volume of GMO(s) administered per dose;
- persons or classes of person that will administer the GMO (e.g., nurses, specialist medical doctors);
- training and experience of persons administering the GMO relevant to minimising their likelihood of exposure, e.g., training and experience in the specific procedure to be undertaken, training in Sharps Injury Prevention;
- any additional persons present during the procedure (e.g., surgical assistant, parent or carer);
- step-by-step description of the administration procedure, including materials used to administer the GMO and details of any steps where sharps handling is required;
- specific PPE to be worn during the procedure by the person administering the GMO, the trial participants and any additional persons present;
- details of post-administration procedures that would remove or contain residual GMO (e.g., flushing an intravenous line with saline, swabbing an injection site and covering with an occlusive dressing); and
- if an occlusive dressing is used to cover an inoculation site, when it will be removed, by whom, and the method of disposal.

Enter text

13.6. Schedule of visits

Provide information on the schedule of follow up visits to the clinical trial site, including timing and activities to be undertaken. Include all planned visits to the clinical trial site and other locations, such as for sample collection at local pathology collection centres.

Enter text

13.7. Collection and analysis of biological samples

Limit this response to collection and analysis of biological samples for the purpose of the proposed clinical trial, including:

- types of sample to be collected and collection times;
- whether viable GMO(s) are likely to be present in sampled materials at any of those times;
- persons or class of persons who will collect the samples (e.g., clinical trial nurses, pathology collection centre staff);
- a description of the process for collecting samples, including any steps where sharps handling is required;
- specific PPE to be worn during sample collection, and any other safety equipment that will be used; and
- a description of any sample processing steps to be undertaken by clinical trial staff.

Note: Collection of biological samples during home nursing visits would generally be approved only where the GMO is not expected to be present in the samples at the time of collection.

Enter text

13.8. Additional measures to minimise the potential for dissemination of the GMO(s)

Describe any additional precautions intended to minimise opportunities for people other than trial participants, and for animals, to be exposed to the GMO. These include people at the clinical trial site not considered in Parts 13.4, 13.5 and 13.7 above, caregivers and close contacts of trial participants, the general public, and household pets, livestock or wildlife in proximity to trial participants.

Enter text

14. Information for trial participants

Describe any instructions to be given to participants and/or carers intended to minimise the potential for dissemination of the GMO(s).

For example:

- instructions for caring for the GMO administration site and disposal of dressings;
- hygiene measures to be implemented for a specified period to minimise transmission of the GMO to other people or to animals;
- restrictions placed on interaction with or proximity to susceptible animal species;
- restrictions placed on close contact with at-risk classes of people, such as infants and those who are immunosuppressed, pregnant or elderly;
- behavioural measures to minimise contact with insect vectors involved in transmission of the parent organism, and/or restrictions placed on travel to locations in Australia where insect vectors are found;
- requirements to use a barrier method of contraception for a specified period; and
- restrictions placed on donation of blood, organs or tissues, or sharing needles with other people, for the duration of the treatment period and a specified time afterwards.

Enter text

15. Facilities to be used during the clinical trial

15.1. Provide details of facilities proposed to be used at each stage of the clinical trial, including the following:

- storing and distributing the GMO(s);
- preparing the GMO(s) for administration;
- administering the GMO(s) to trial participants;
- collecting biological samples from trial participants; and
- analysing biological samples from trial participants (if taking place in Australia).

Where specific facilities are not yet known, please indicate the type of facility to be used.

Note: Add rows to the table as required.

Facility name (if known) or class of facility	OGTR certification number (if applicable)	Type of facility	Activities to be undertaken in the facility
		E.g., storage and distribution provider	E.g., unpacking the GMO, storage, repackaging for shipment to clinical trial sites
		E.g., hospital pharmacy	E.g., storage, preparing the GMO for administration to participants
		E.g., hospital procedure room	E.g., administering the GMO to trial participants
		E.g., hospital pathology laboratory	E.g., analysis of biological samples containing the GMO

16. Storage of the GMO(s)

This question applies to storage of GMOs within storage/distribution facilities, at clinical trial sites and at analytical facilities (if relevant). Please indicate how you propose to ensure containment of the GMO(s) during storage, and manage risks associated with storage of the GMO(s), by completing the table below.

Will the GMO(s) be stored in accordance with the following?	**Response**			**For any aspect of storage that will not be in accordance with the indicated item, describe how the GMO(s) would be handled instead.**
The GMO will be contained within a sealed[3], unbreakable[4] primary container.	☐ Yes	☐ No		
The GMO will be contained within a sealed[3], unbreakable[4] secondary container (required for GMOs whose parent organism satisfies the criteria for classification of a RG2 organism described in AS/NZS 2243.3).	☐ Yes	☐ No	☐ Not applicable	
The outer packaging in which the GMO is stored will be labelled to indicate at least:				
i) that it contains GMOs	☐ Yes	☐ No		
ii) that it contains biohazardous material as designated by a biohazard label (required for GMOs whose parent organism satisfies the criteria for classification of a RG2 organism described in AS/NZS 2243.3)	☐ Yes	☐ No	☐ Not applicable	
iii) the contact details for the licence holder	☐ Yes	☐ No		
iv) instructions to notify the licence holder in case of loss or spill of the GMOs	☐ Yes	☐ No		

[3] As defined in the Regulator's *Guidelines for Transport, Storage and Disposal of GMOs*
[4] As defined in the Regulator's *Guidelines for Transport, Storage and Disposal of GMOs*

If the GMO is being stored with a coolant (e.g., dry ice or liquid nitrogen) that will release a gas, the packaging will include a mechanism to allow the gas to escape. If water ice is used as a coolant then the outer packaging will be constructed so as to prevent any leakage. All containers will be able to withstand the temperatures to which they will be subjected.	☐ Yes ☐ No ☐ Not applicable	
A consolidated record of all stored GMOs will be maintained.	☐ Yes ☐ No	
Procedures will be in place to ensure that all stored GMOs can be accounted for, and that a loss of GMOs during storage can be detected.	☐ Yes ☐ No	
Access to the GMOs will be restricted to authorised persons conducting dealings under the licence, who have been informed by the licence holder of any licence conditions that apply to them.	☐ Yes ☐ No	

17. Transport of the GMO(s)

Please indicate how you propose to ensure containment of the GMO(s) during transport, and manage risks associated with transport of the GMO(s), by completing sections 1-3 in the table below.

1. Transport in accordance with IATA requirements

Note: Information about International Air Transport Association (IATA) packaging requirements can be found in IATA's Infectious Substances Shipping Guidelines.

Will transport associated with import and export of the GMO(s) be conducted in accordance with IATA requirements?	Applicable?	Transport will follow IATA requirements (provide UN classification and packing instruction number)	For any aspect of the listed transport that will not be in accordance with IATA requirements, describe how the GMO(s) would be handled instead.
Import of GMO(s), between the Australian border and premises of the addressee	☐ Yes ☐ No	☐ Yes for UN ____ and packing instruction ____ ☐ No	
Export of unused GMO(s) (e.g., to product sponsor) between premises of the sender and the Australian border	☐ Yes ☐ No	☐ Yes for UN ____ and packing instruction ____ ☐ No	
Export of participant samples containing the GMO(s) for analysis overseas, between premises of the sender and the Australian border	☐ Yes ☐ No	☐ Yes for UN ____ and packing instruction ____ ☐ No	
Any other transport – please describe: _____	☐ Yes	☐ Yes for UN ____ and packing instruction ____	

2. Transport for the purpose of disposal via the clinical waste stream			
Will waste* that is decontaminated/disposed of by external service providers be removed from clinical trial sites via the clinical waste stream? **Note: This includes discarded GMO (e.g., unused product) and waste contaminated with the GMO.*	☐ Yes ☐ No		Transport for the purpose of offsite waste disposal that is not via the clinical waste stream is addressed in section 3 of this table.

3. Any other transport

Will the types of transport listed below be conducted in accordance with the following requirements?

1. The GMO will be contained within a sealed, unbreakable primary container;
2. GMOs whose parent organism satisfies the criteria for classification of a RG2 organism described in AS/NZS 2243.3 will also be contained within a sealed, unbreakable secondary container;
3. The outer packaging will be labelled to indicate at least:
   a) that it contains GMOs;
   b) for GMOs whose parent organism satisfies the criteria for classification of a RG2 organism described in AS/NZS 2243.3, that it contains biohazardous material as designated by a biohazard label;
   c) the contact details for the licence holder; and
   d) instructions to notify the licence holder in case of loss or spill of the GMOs;
4. If the GMO is being transported with a coolant (e.g., dry ice or liquid nitrogen) that will release a gas, the packaging will include a mechanism to allow the gas to escape. If water ice is used as a coolant then the outer packaging will be constructed so as to prevent any leakage. All containers will be able to withstand the temperatures to which they will be subjected;
5. The external surface of the primary and secondary container will be decontaminated before and after transport;
6. Procedures will be in place to ensure that all transported GMOs can be accounted for, and that a loss of GMOs during transport can be detected; and
7. Access to the GMOs will be restricted to authorised persons conducting dealings under the licence, who have been informed by the licence holder of any licence conditions that apply to them. This includes situations where containers are left for collection in a holding area.

Types of transport	Applicable?	Transport will be in accordance with the listed requirements for appropriate risk group	For any aspect of transport that will not be in accordance with the listed requirements, describe how the GMO(s) would be handled instead
Transport of GMO(s) or samples containing GMO(s) between physically distinct sites, e.g.: - third-party storage facility to clinical trial sites - between clinical trial sites - clinical trial sites to analytical facilities	☐ Yes ☐ No	☐ Yes ☐ No	
Transport of GMO(s) within a storage or clinical trial site, e.g., between storage rooms, pharmacy, preparation area and clinical area *Note: items 3 (b)-(d) and item 6 are not required if this transport takes place entirely within a building.*	☐ Yes ☐ No	☐ Yes ☐ No	
Transport of waste containing the GMO(s) by external service providers, for off-site decontamination/disposal, that is not via the clinical waste stream *Note: This includes discarded GMO (e.g., unused product) and waste contaminated with the GMO.*	☐ Yes ☐ No	☐ Yes ☐ No	
Any other transport – please describe: _____	☐ Yes ☐ No	☐ Yes ☐ No	

18. Destruction of the GMO(s)

Please indicate how you propose to destroy the GMO(s) by completing the table below. Consider unused GMO, residual GMO left over after administering to trial participants, clean-up of work areas, and decontamination of equipment or waste reasonably expected to contain the GMO(s) (e.g., reusable PPE and equipment, single use PPE, syringes, needles, cannulas, dressings etc). If methods will vary across different clinical trial sites, include all proposed methods.

Will the GMO(s) be destroyed in accordance with the following items?	**Response**	**For any aspect of destruction not in accordance with the indicated item, describe how the GMO(s) would be destroyed instead.**
GMO(s) at clinical trial sites, storage/distribution facilities and/or analytical facilities will be destroyed onsite either by chemical treatment (e.g., using chemical disinfectants to treat work areas and reusable equipment) or by autoclaving.	☐ Yes ☐ No	
GMO(s) to be treated by external service providers will enter the clinical waste stream for destruction by the indicated method.	☐ Yes ☐ No Method ☐ Incineration ☐ Autoclaving ☐ Other (please describe):	
GMO(s) to be treated by external service providers will be removed from clinical trial sites, separate from the clinical waste stream, for destruction by the indicated method.	☐ Yes ☐ No Method ☐ Incineration ☐ Autoclaving ☐ Other (please describe):	

19. Contingency plans

Provide details of your contingency plans in case of unintended release of or exposure to the GMO(s). Events that may lead to unintended release of or exposure to the GMO include:

- a spill of the GMO(s) or of waste that contains the GMO(s);
- exposure of a person carrying out authorised activities with the GMO(s) in the course of their work e.g., through needle stick injury, inhalation or splash during dose preparation or administration to trial participants; and
- transmission of the GMO(s) from a trial participant to another person or to a susceptible animal.

19.1. Contingency plans in the event of a spill of the GMO(s)

Please indicate whether you can comply with the following standard procedures to manage spills that may occur in storage and distribution facilities, clinical trial sites and associated pharmacies or laboratories. Consider all activities where staff associated with the clinical trial are in possession of the GMO(s) e.g., unpacking, storage and repackaging prior to distribution; preparation of the GMO for administration in a laboratory or pharmacy; administration of the GMO to trial participants; and storage of waste at clinical trial sites while awaiting collection by waste contractors.

Will the following spill management procedures be implemented?	Response
• The GMO(s) will be contained to prevent further dispersal • Persons cleaning up the GMO(s) will wear protective clothing • The exposed area will be decontaminated with an appropriate chemical disinfectant effective against the GMO(s) • Any material used to clean up the spill or personal protective clothing worn during clean-up of the spill will be decontaminated • Clinical trial staff will notify the licence holder as soon as reasonably possible following the spill • The licence holder will notify the Regulator as soon as reasonably possible after being notified that the spill occurred	☐ Yes ☐ No

If Yes, provide details of protective clothing and any other protective equipment to be used while cleaning up the GMO(s):

Enter text

If No, provide details of alternative spill management procedures that you intend to follow:

Enter text

19.2. How do you intend to manage inadvertent exposure of persons conducting dealings in the event they are exposed to the GMO(s) by the following routes?

Describe the contingency plans for management of accidental exposure that you will recommend to clinical trial sites and other organisations involved in the trial.

Note: The OGTR recognises that final contingency plans will need to align with Occupational Health and Safety policies and procedures in place at individual sites. Responses are only needed where exposure via the indicated route could lead to transmission of the GMO.

Route of exposure	Protocol
Sharps injury or contact with broken skin	E.g., encourage bleeding of site, wash with soap and water and provide the following medical attention <details>. Incident would be reported to the Principal Investigator, who would report to the licence holder within <?> timeframe. The licence holder would then notify the Regulator.
Aerosols or airborne droplets, inhalation	
Aerosols or airborne droplets, direct contact with facial mucosa	
Ingestion	
Other (specify)	

19.3. What protocols will be in place to detect and address transmission of the GMO(s) from a trial participant to another person?

Enter text

19.4. What protocols will be in place to detect and address transmission of the GMO(s) from a trial participant to an animal?

Note: a response is only required for GMOs capable of infecting animal species found in Australia.

Enter text

20. Additional information about the parent organism

For each parent organism <u>not</u> previously assessed by the OGTR and listed in part 9.3, provide the following details. If you need to describe more than one parent organism, please duplicate these pages as required.

20.1. Biology and life habit

Provide a brief description of the parent organism, including its life habit (e.g., pathogenic, parasitic, commensal, etc.) and any sequence of life stages the organism undergoes.

Enter text

20.2. Genome

Describe how the genome is organised, including the presence of any plasmids and their characteristics. For viruses, include whether the genome is DNA or RNA-based, number and polarity of nucleic acid strands, genome size, number of genes and mode of replication.

Enter text

20.3. Reservoir and host range

Describe the population of host organisms or the specific environment in which the parent organism naturally lives and reproduces, or upon which the parent organism primarily depends for survival. Describe any other organisms that can harbour or be infected by the parent organism.

Enter text

20.4. Geographic distribution

Is the parent organism native to, endemic in, or not present in Australia? Describe where in Australia the parent organism and closely related organisms (e.g., related viruses that may be capable of recombination with the GMO) can be found, and their prevalence near the proposed clinical trial sites.

Enter text

20.5. Cell tropism

Describe which cells and tissues of the body are colonised or infected by the parent organism, or in which the parent organism can replicate.

Enter text

20.6. Transmission

Describe the way the parent organism is transmitted between host organisms, e.g. via aerosols, soiled material, direct contact with blood, via insect vectors, etc. Where relevant, identify the life stage(s) of the organism that are involved in transmission.

Enter text

20.7. Insect vectors

Where relevant, provide details of insect vectors involved in transmission of the parent organism, including identities of competent (or potentially competent) vector species.

Describe the availability and geographic distribution of competent (or potentially competent) vector species in Australia. Discuss their prevalence near proposed clinical trial sites and anticipated catchment areas for trial participants.

Enter text

20.8. Pathogenicity and/or effects on humans and other organisms found in the environment

Describe the effect of the parent organism on infected, colonised or parasitised organisms. If the parent organism is a pathogen, include details of infectious dose, incubation period, and disease symptoms in affected species.

Enter text

20.9. Susceptibility within the human population

Describe any sectors of the human population that are particularly susceptible to infection or colonisation by the parent organism (e.g., immunocompromised or elderly people, pregnant women, infants, foetuses etc).

Enter text

20.10. Decontamination and treatment options

Describe effective methods to kill or inactivate the parent organism and to treat a person or animal who has been exposed to the parent organism. If the strain to be used is resistant to any treatments (e.g., to specific antibiotics), provide details.

Enter text

20.11. Persistence in the environment

Describe the ability of the parent organism to persist in the open environment and to make dormant forms such as spores or microbial cysts.

Enter text

20.12. Genome recombination and Horizontal Gene Transfer

For viruses, describe the scope and frequency of genome recombination events within the same species and with related species. For bacteria, explain whether the parent organism is capable of exchanging genetic material through mechanisms of Horizontal Gene Transfer (i.e., transformation, transduction and conjugation) and the frequency of such transfer events.

Enter text

20.13. Genomic integration

Can the parent organism's genome integrate into the genome of a host cell? If so, describe the process and frequency of this event.

Enter text

20.14. Risk group and containment

Provide the Risk Group classification and recommended physical containment level for the parent organism, according to the criteria described in the current version of AS/NZS 2243.3.

Enter text

21. Checklist of attached documents

Please ensure the following documents are provided with the completed licence application form:

☐ Applicant organisation's financial statement (Part 5)
☐ Signed Declarations page (Part 7)

Any application for a Declaration that specified information is CCI should be submitted at the same time as this licence application.