Australian Government
Department of Health
Office of the Gene Technology Regulator

Application for a licence

for dealings with a GMO not involving intentional release of the GMO into the environment (DNIR)

Title of the project:

Applicant Organisation Name:

Guidance Notes: Subject to a licence being issued, the organisation applying for the licence (and not the project supervisor) will be the licence holder. Licence conditions apply to persons covered by the licence. Such persons may include the project supervisor, and employees, contractors or agents of the licence holder.

Accreditation Number*:

* Where the organisation is accredited by the Gene Technology Regulator

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

Yes		No	

If the CCI is covered by previous CCI application(s), please provide the CCI or DNIR application number(s) here:

Time taken to complete this form:

Hours		Minutes	

File number: . . . . . [OGTR use only]

Application ID:. . . . . [OGTR use only]

Information for applicants

We encourage prospective applicants to contact the Office of the Gene Technology Regulator (OGTR) before submitting an application to advise you on the classification of GMO dealings and in selecting the appropriate application form, and to discuss information requirements. You can call (1 800 181 030) or email.

What is this application form for?

This application form must be used for applications for a licence for dealings (activities) NOT involving the intentional release (DNIR) of a GMO into the environment. DNIRs are usually conducted in certified containment facilities, and do not meet the criteria for Exempt dealings or Notifiable Low Risk Dealings (NLRDs) in the *Gene Technology Regulations 2001* (the Regulations). Schedule 3, Part 3 of the Regulations describes what kind of work is classified as DNIRs.

What information do you need to provide?

This application for a licence must contain correct and adequate answers. You must answer each question unless otherwise instructed.

The Regulator is not required to consider applications for a licence which do not contain the information specified.

If you wish to protect any information in this form from public disclosure, you must also fill out an *Application for declaration that specified information is confidential commercial information (CCI)* form. Please submit it together with this DNIR licence application form. Further explanatory material with respect to the information requirements associated with a CCI application is provided on the *Application for declaration that specified information is CCI* form.

What will we use the information provided in this form for?

We will use the information in the application form to prepare a Risk Assessment and Risk Management Plan (RARMP) in relation to the proposed activities. The Regulator's decision whether or not to issue a licence, and conditions to impose if a licence is issued, is based on the RARMP.

Information in this application may be provided to other Federal or State government agencies or to experts as part of the Regulator's evaluation of the application, and it may be released to the public under certain limited circumstances, e.g. in response to a Freedom of Information request.

What is the application fee for a DNIR application?

There is currently no application fee.

How should you fill out this form?

- We prefer you sending your application electronically in a searchable format.
- Ensure you answer each relevant question in sufficient detail. Not providing the required information could delay a decision, or the Regulator may not 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 answer each question with adequate supporting material. Scientific information should be comprehensive and supported by whatever data and references are available.
- Do not repeat information. If necessary, refer to your answer to other questions.
- Contact us if you have any questions or would like our comments on a draft application.

How can you submit this form?

Once you have obtained the relevant signatures, you can submit a hard copy or an electronic copy:

- **by email** to: ogtr.applications@health.gov.au
- **by mail** to: Office of the Gene Technology Regulator, MDP 54, GPO Box 9848, Canberra, ACT, 2601.

Please keep a copy of the application for your records.

You should note that if you email an application containing sensitive information (such as CCI), it will be 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 as appropriate. If you wish to make alternative arrangements to securely transmit CCI information, please contact this office.

What will happen after you have submitted the application?

We will acknowledge receipt of the application by email and assign it an OGTR reference number. Please cite this reference number whenever you contact us regarding the application.

Please contact us if we have not confirmed receipt within two weeks of submission.

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

The Regulator must make a decision to issue, or to refuse to issue, a licence for a DNIR licence application within 90 working days.

We may ask you for additional information in relation to your application. Any days on which the Regulator cannot proceed with decision making while awaiting requested information do not count for purposes of determining the end of the decision-making period. The Regulator may cease to consider your application if you fail to provide requested information within the specified timeframe.

Disclosure of information

With the exception of personal, security sensitive or confidential commercial information, details of licences issued by the Regulator will be published on the OGTR website at http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/contained-1.

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Personal Information

Personal information is collected by the OGTR to enable the Gene Technology Regulator to perform the functions set out the *Gene Technology Act 2000* (the Act). Personal information specified 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 can be accessed at the Department of Health's APP privacy policy web page. The Department's APP privacy policy explains detail how the Department 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.

Part 1: Contact Person for the Application

The contact person must be authorised by the applicant to act on their behalf in relation to this application and, subject to a licence being issued, any applications for variation of the licence.

Surname:		First name:	
Personal title: (e.g. Ms/Mr/Dr)		Job title:	
Phone number:		Fax number:	
Mobile number:		E-mail Address:	
Street number and name:			
Town/City:		State:	
Postcode:		Country:	
Postal address: (if different from above)			

Part 2: Project supervisor and/or technical contact

Contact details

Surname:		Preferred first name:	
Personal title: (e.g. Ms/Mr/Dr)		Job title:	
Phone number:		Fax number:	
Mobile number:		E-mail address:	
Building name: (if applicable)			
Street number and name:			
Town/City:		State:	
Postcode:		Country:	
Postal address: (if different from above)			
Brief details of technical knowledge and skills relevant to the application (*optional*)			

Guidance Notes:

1. The person(s) nominated in this Part may be contacted by staff from the OGTR as part of the licence application assessment. In many cases, the most appropriate person to contact would be the project supervisor. However, other persons with suitable technical knowledge and skills relevant to the proposed dealings may be more appropriate to contact in relation to the licence application. If so, please enter their contact details in this section.
2. The person(s) nominated in this Part will not be taken to be authorised to make variation applications unless they are also listed as contact persons in Part 1 above.
3. If you wish to list more than one project supervisor/technical contact, please duplicate this page for each person listed.
4. If additional persons are listed in this Part, please provide brief details of their knowledge and skills relevant to the licence application. This will allow OGTR staff to contact the most relevant person if further information is needed.
5. Subject to a licence being issued, the person(s) listed here may be contacted regarding monitoring of the licence. Please consider whether additional persons with appropriate technical knowledge and skills could be listed for this purpose.

Part 3: Applicant Organisation type

Is this application being made by;

(a) a natural person, or	
(b) an organisation	

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

Note: Your response to this question is necessary to determine whether the Regulator will issue the licence under Commonwealth legislation or under corresponding State law. If unsure you should seek legal or other advice which will accurately identify the legal status of the organisation.

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

Yes		No	

2. A Commonwealth authority.

Yes		No	

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

(a) a body corporate established for a public purpose by or under an Act;	
(b) a company in which a controlling interest is held by any one of the following persons, or by 2 or more of the following persons together:	
(i) the Commonwealth;	
(ii) a body covered by paragraph (a);	
(iii) a body covered by either of the above subparagraphs.	

3. A State Government Agency:

Yes		No	

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

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

4. A Higher Education Institution:

Yes		No	

5. Other:

Yes		No	

If you have indicated 'other' please answer the following questions:
Does your organisation have a legal personality i.e. can *the organisation* sue and be sued, sign contracts etc. in its own name?

Yes		No	

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

Please provide details in the space below.

Part 4: Suitability of the applicant

Has the applicant, within a period of ten years immediately before the making of the application for this licence, been convicted of an offence against a law of the Commonwealth, a State or a foreign country which relates to the health and safety of people or the environment which is 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 - please provide details of the following in an attachment and indicate attachment number:

- The Act the offence was committed under,
- The date the offence was committed,
- The date of the conviction,
- The penalty which was imposed.

Attachment #

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 ☐ No ☐ If Yes - provide director's name

(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 ☐ No ☐ If Yes - provide person's name

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 ☐ No ☐ If Yes - please provide details in an attachment and indicate attachment number

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

Yes ☐ No ☐

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

dd/mm/yyyy

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

Note: 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.

dd/mm/yyyy

Has a copy of the applicant's latest financial statement been provided with this application together with either a copy of 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?

Yes		No	

Note: Applicants are required to supply the required financial information before this application will be considered by the Regulator. If available, an electronic copy of the financial statement can be provided (for example, by providing the URL for the statement on the internet).

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		No		If Yes - please provide details in an attachment and indicate attachment number	

Part 5: Supporting information from the Institutional Biosafety Committee (IBC)

This part must be completed by the IBC responsible for the Applicant Organisation.

Name of IBC:	
Name of Chairperson of IBC:	
Contact details of chairperson of IBC – phone number:	
Facsimile number:	
E-mail address:	
Name of IBC Primary Contact:	
Contact details of IBC Primary Contact, Phone number:	
Facsimile number:	
E-mail address:	
Date of IBC evaluation of this application:	dd/mm/yyyy
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 – if no please provide details in an attachment and indicate attachment number –
Has the information contained in this form been checked by the IBC and found to be complete?	☐ Yes ☐ No – if no please provide details in an attachment and indicate attachment number –
Does the IBC consider that the personnel intended to be involved in dealing(s) with the GMO(s) have adequate training and experience for the proposed dealings?	☐ Yes ☐ No – if no please provide details in an attachment and indicate attachment number –

Which paragraph(s) of Schedule 3 Part 3 of the *Gene Technology Regulations 2001* have the IBC assessed as applying to the proposed dealings?

Please select as many as are applicable.

Part 3.1:

- ☐ (a)
- ☐ (b)
- ☐ (c)
- ☐ (d)
- ☐ (e)
- ☐ (f)
- ☐ (g)
- ☐ (h)
- ☐ (i)
- ☐ (j)
- ☐ (k)
- ☐ (l)
- ☐ (m)
- ☐ (n)
- ☐ (o)
- ☐ (p)

Other (please specify):

What level of containment is appropriate for these dealings

Please select as many as are applicable.

- ☐ PC1
- ☐ PC2
- ☐ PC3
- ☐ PC4

Other (please specify):

What facilities are appropriate for the dealings?

Please select as many as are applicable.

- ☐ Laboratory
- ☐ Animal Facility
- ☐ Plant Facility
- ☐ Large Scale Facility
- ☐ Large Grazing Animal Facility
- ☐ Aquatic Organism Facility
- ☐ Invertebrate Facility
- ☐ Constant temperature room

Other (please specify):

Part 6: Declarations

I DECLARE THAT:

- I am duly authorised to sign this declaration; and
- the information supplied on this form and any other attachment is true and correct.

CEO (or delegate with authority to sign) of the Applicant Organisation

Printed name:		Signature:	
Job title:		Date:	

Project Supervisor

Printed name:		Signature:	
Job title:		Date:	

IBC Chair

Printed name:		Signature:	
Job title:		Date:	

Part 7: About the dealings with the GMO(s)

In this part you are required to describe the dealings with the GMO(s) proposed to be authorised by the licence. This will provide the Regulator with the context for preparation of a Risk Assessment and Risk Management plan.

Title of the project:

Preferred duration of licence:
(Note: The initial period for a licence is a maximum of 5 years)

Description of proposed dealing(s) with the GMO(s):

Please select from the following list of dealings those that best describe the proposed dealings (more than 1 can be selected).

- ☐ conduct experiments with the GMO
- ☐ make, develop, produce or manufacture the GMO
- ☐ breed the GMO
- ☐ propagate the GMO
- ☐ use the GMO in the course of manufacture of thing* that is not a GMO

  Is the thing* subject to regulation by other agencies? (e.g. Food Standards Australia, Australian Pesticides and Veterinary Medicines Authority, Therapeutic Goods Administration)

  ☐ Yes (please provide details and indicate attachment in which details are provided)

  ☐ No

  (*As defined in the Gene Technology Act 2000)
- ☐ grow, raise or culture the GMO
- ☐ import the GMO

  Is the import subject to AQIS approval?

  ☐ Yes

  ☐ No
- ☐ transport the GMO
- ☐ dispose of the GMO

Description of purposes and aims of the proposed dealing(s): Describe the aims of the proposed dealing in one or two sentences of plain English.	
Specify person, persons or class of persons intended to be authorised to undertake dealing(s) with the GMO(s):	

Will any of the proposed dealing(s) involve the intentional release of GMO(s) into the environment?*

Yes		No	

*If you answered yes to this question you may require a licence for a Dealing involving an Intentional Release of GMOs into the environment (DIR). Information regarding DIR licences can be found on the OGTR website at http://ogtr.gov.au/internet/ogtr/publishing.nsf/Content/dirclass-2

Will any of the proposed dealings with GMOs involve the use of nanotechnology*, or inclusion or production of engineered nanomaterials**?

Yes		No	

*** Nanotechnology** is engineering at the atomic or molecular level, involving the manipulation of matter at the nanoscale (generally accepted as 100 nanometres or less) to create new materials, structures and devices. For the purpose of this question, nanotechnology does not include standard techniques of molecular biology/gene technology.

**** Engineered nanomaterials** are materials designed at the molecular level to take advantage of novel properties which are generally not seen in their conventional counterparts.

The Australian Government has committed to taking a proactive approach in monitoring developments in nanotechnology so as to ensure the regulatory frameworks charged with protecting public health, safety and the environment keep pace with these changes.

Information about the dealings with the GMO(s)		Attachment
7.1	**Details of the scientific background of the proposed dealings:** If possible, limit your answer to one page. Copies of key papers and any other data that may assist the assessment process should also be submitted (see also Part 15: References). Please provide sufficient information for the proposed dealings to be understood in the context of the overall scientific project.	
7.2	**Details of your work:** For the proposed dealings with the GMO provide an outline of the experiments, including experimental design and techniques to be used. Sufficient detail must be provided to enable any potential risks posed by the dealings to be identified and assessed. Details should include: • Information on whether the dealings are *in vitro* and/or *in vivo*; • The method(s) of administration or exposure to the GMOs (where relevant); • The scale/volume of the dealings; • The acquisition and the proposed fate of the GMO(s). You may use dot points in your answer.	

Part 8: Physical containment of the GMO(s)

For each facility proposed to be used for the dealings please provide the following details as an attachment and indicate attachment number –

	Attachment #
Name of facility:	*(This will be the same as that on the notice of certification)*
Facility type:	*[For example, animal containment facility, laboratory, plant containment facility etc]*
Physical containment level:	*[PC2, PC3, PC4 etc]*
Date of certification:	
Certification number:	
Date of most recent inspection:	
Who undertook the inspection:	*[Indicate if it was the OGTR, the IBC, or a representative of the IBC]*

Facility address details:

Street address:	

Facility contact person details:

Name:	
Business phone number:	
Mobile phone number:	
Facsimile number:	
E-mail address:	

Part 9: Description of the GMO(s)

For each GMO provide an Attachment with the following information as set out below. Clearly label the information and indicate the relevant attachment:

GMO #	Parent Organism Name	Attachment #

Information	
9.1	**What is the common and scientific name(s) of the parent organism(s)?** The "parent organism" means the organism (including cells) that you propose to genetically modify. In the case of dealings involving replication defective viral vectors this would include the parent virus, the packaging cells used to construct the vector particles, and the intended host cells (e.g. tissue culture cells or host animal cells transduced by the vector).
9.2	**If the parent organism is a pathogen, please provide details about the following:** **i. Environmental stability;** **ii. Virulence/pathogenicity;** **iii. Host range;** **iv. Transmissibility;** **v. Treatment options.**
9.3	**What vectors and/or methods are to be used for the transfer of genetic material?** Please provide copies of references (or vector maps) for novel vectors or methods of transfer. Also include the name of the company supplying any commercially obtained vectors and relevant documentation produced by the supplier. For dealings involving viral vectors, and where applicable, please provide information on the following: • the plasmid(s) to be used • the genes deleted from the parent virus • the accessory genes supplied *in trans* • self-inactivation sequences.
9.4	**Please provide the following details about the genetic material that will be inserted, deleted or modified in the parent organism:** **i. Identity of the genetic material;** **ii. Common and scientific names of the source (donor) of the genetic material;** **iii. Function of the genetic material (where known).** Please include details of any genes and associated genetic elements e.g. promoter/enhancer elements, introns, polyadenylation sequences. Where the introduced genetic material is intended to knock out the expression/function of an endogenous gene, please include details of the endogenous gene and its function. If site-directed mutagenesis is to be used, please include details about the unmodified gene and expected effects of the mutagenesis, where known. This level of information is not required about gene(s) commonly used as markers, for selection and/or any other routine procedures. However it is of interest to identify generally which type of gene will be used. For example, *amp* gene (ampicillin resistance), *neo* gene (neomycin resistance), *gfp* gene (green fluorescent protein) etc. Where the introduced genetic material is involved in the production of a known toxin, or has been implicated in a toxic effect, please include relevant details and toxicity data.

9.5	**Where the source (donor) of the genetic material is capable of causing disease in humans, animals, plants or fungi, please provide the following details on the role the genetic material plays in the donor's:** **i. Environmental stability;** **ii. Virulence/pathogenicity;** **iii. Host range;** **iv. Transmissibility;** **v. Treatment options.**
9.6	**Details of the effect of the genetic modification upon the parent organism:** Please include the resultant modified trait(s) and also the expected effects upon the phenotype of the parent organism. Where the parent organism is a pathogen, please also address the known or potential effects of the genetic modification upon the traits listed in 9.2 and 9.5 (i – v).
9.7	**What organisms, tissues or cells are to be used in association with the GMO(s)?** Examples include tissue culture cells, animal species (including insects), plant species, and human beings. Note that if animals, plants or people are involved in these dealings; please complete Part 11, Part 12 or Part 13, respectively.
9.8	**If the GMO is being used to generate a thing that is not a GMO, what is the GM product and how is it proposed to be used?** Examples of GM products include: human and veterinary therapeutics, industrial chemicals and stockfeed.
9.9	**How do you propose to dispose of/destroy the GMO?** Please include proposed decontamination/disposal methods for any equipment or waste contaminated with the GMO.
9.10	**Is there any further information that you are aware of regarding the nature of the GMO(s)?** Information that you provide here will help to reduce the level of the uncertainty in the risk assessment. Examples of additional information: • The site within the parent organism's genome where the genetic modification has taken place; or • The identity of any genes known to have been disrupted due to the insertion of the genetic material.

Part 10: Additional information if the volume of a single GMO culture exceeds 25 litres

Will any of the proposed dealing(s) involve cultures of GMO(s) in excess of 25 litres?

Yes ☐ No ☐

Please provide the information for each GMO where the volume exceeds 25 litres.

Information		Attachment
10.1	**What are the main product(s) to be isolated?**	
10.2	**Please describe the production process, including the following details:** **i. The fermentation mode (if applicable);** **ii. The expected volume of GMOs and frequency of production;** **iii. Any post-fermentation processing, including the expected viability of the GMO at each stage**	
10.3	**Will the genetic stability of the GMO be checked? If yes, how will this be done and at what frequency?** This relates to monitoring strategies to detect possible mutations, recombinations or other unforeseen effects.	
10.4	**Is the facility to be used a certified large-scale facility?** If not, please provide justification for the proposed containment level and type, including details on: i. Design of the facility; ii. Containment equipment; iii. Proposed decontamination procedures for large scale volumes; iv. Training procedures; v. Emergency procedures.	
10.5	**What precautions will be taken to prevent any unintended dispersal of the GMO?**	
10.6	**What methods will be used for decontamination/disposal of the GMO?**	

Part 11: Additional information for a GMO that is a whole plant or is to be used in conjunction with a whole plant

Will any of the proposed dealing(s) involve a GMO that is a whole plant or is to be used in conjunction with a whole plant?

Yes ☐ No ☐

Information		Attachment
11.1	**If the parent organism is a plant please address the following questions:** **i. Is the parent organism a weed or closely related to plants that are weeds? If yes, please provide details on the weediness of the plants/relatives;** **ii. Does the plant produce any known toxins or allergenic products? If yes, please provide details, including the known or potential effects of the genetic modification on these products;** **iii. Are related plant species present in the area immediately surrounding the location for the proposed dealing?** **iv. What stage of development will the plants be grown to?** **v. What measures are proposed to prevent the dissemination of plant propagative material?**	
11.2	**What methods will be used for decontamination of GMOs?**	
11.3	**What methods will be used for the disposal of any material used in conjunction with the GMOs?** This includes any plants, plant propagative material, liquid effluent or plant growth medium used.	
11.4	**Is the facility to be used a certified plant facility?** If not, please provide justification for the proposed containment level and type, including details on: i. Design of the facility; ii. Containment equipment.	

Part 12: Additional information for a GMO that is an animal or is to be used in conjunction with an animal

Will any of the proposed dealing(s) involve a GMO that is an animal or is to be used in conjunction with an animal?

Yes ☐ No ☐

Information		Attachment
12.1	**What is the number of genetically modified animals and/or the number of other animals to be used?** Include numbers of animals per proposed experiment.	
12.2	**How will the animals be identified?** Examples include the use of labels on cages or, for larger animals, branding or tattooing.	
12.3	**If a GMO is to be administered to an animal, please address the following questions:** **i. Please describe the administration process, including:** **a. How will the animals be restrained?** **b. Will any sharp instruments be used?** **c. If there is the potential for aerosol generation, how will the aerosols be contained?** **ii. Will the GMO be secreted or excreted from the animal? If yes, please provide details, including the proposed method for containment of the animals and GMO (including any aerosols);** **iii. What personal protective equipment will be used?**	
12.4	**What are the proposed methods for decontamination and disposal of the GMO, animals used in conjunction with the GMO, and waste containing the GMO?** Please include strategies for preventing the release of the GMO into the environment and the effectiveness of these strategies. Also indicate which decontamination methods or agents are effective against the GMO.	

Part 13: Additional information for a GMO that is for use in human clinical trials

Will any of the proposed dealing(s) involve the introduction of GMOs into human beings?*

Yes ☐ No ☐

*If yes, please contact the OGTR prior to submission to discuss the data requirements.

Information		Attachment
13.1	**What is the purpose of the clinical trial?** Please include details on the medical condition that is being treated/investigated. If available, please provide information on any related clinical trials, including those conducted in other countries.	
13.2	**If the GMO is derived from a microorganism, what is the host range of the parent organism(s) from which the GMO is constructed?** Please include information relating to any replication defective viral vectors to be used.	
13.3	**Please outline the trial protocol:** A copy of the investigator's brochure or clinical protocol should be included with this application (where available).	
13.4	**What is the potential for the genetic material of the GMO to become incorporated (in whole or in part) into the genome of any cells of a treated person?** Please include any replication defective viral vectors in this answer.	
13.5	**Will the GMO multiply in the treated person?** Please include supporting details as to why the GMO will/will not multiply in the treated person.	
13.6	**What is the potential for the GMO to be disseminated into the environment through human excretions and wastes during or after the trial?** Include, but do not limit to, information on: • The duration of shedding; • The potential for dissemination through close personal contact, or to the general population; • Measures intended to be taken to minimise the potential for dissemination; • The viability of the GMO in the environment, including its susceptibility to environmental factors; • The potential for the GMO to cross the placenta of a pregnant person; • The potential for the GMO to be spread through sexual contact; • The potential for the GMO to spread to other species; and • If the potential exists, the likely mechanism and frequency of such spread.	

13.7	**What are the expected effects from exposure to the GMO?** This includes the effects on people, and other species.	
13.8	**If the GMO is a defective virus:** **i. What is its potential for re-acquiring the ability to replicate (by complementation or recombination with host viruses)?** **ii. Will the GMO be tested for replication competence? If yes, please provide details.**	
13.9	**Will any of the dealings be conducted in certified facilities? If not, please detail the key characteristics of the places where the dealings will be carried out (eg doctor's surgeries, clinics, hospital rooms etc) and the role of such places in the containment of the GMO.**	
13.10	**What are the proposed methods for decontamination and disposal of the GMO (including waste containing the GMO)?** Please include strategies for preventing the release of the GMO into the environment and the effectiveness of these strategies. Also indicate which decontamination methods or agents are effective against the GMO.	
13.11	**Has approval for the proposed dealings been sought from a Human Research Ethics Committee (HREC) and, where applicable, the Therapeutic Goods Administration (TGA)?** If yes, please provide the name of the HREC and, if approved, the date(s) of approval by the HREC and TGA.	

Part 14: Risk assessment and risk management

Information		Attachment
14.1	**How could people undertaking the dealings be harmed as a result of the proposed genetic modification(s)? Discuss the seriousness and likelihood of the potential harm.** If appropriate, include comparisons to the unmodified organism. For viruses and viral vectors, include, but do not limit to, information on: i. The replicative ability of the virus/viral vector. If it is replication deficient, what are the modifications responsible for this? ii. The replication properties in different cells and organisms. iii. Infection capability irrespective of its ability to replicate. iv. Information about complementation and recombination.	
14.2	**In relation to health and safety, how could people be harmed from an unintentional release of the GMO(s) into the environment? Discuss the seriousness and likelihood of the potential harm.** This relates to the general population exposed to a GMO that is unintentionally released from containment. If appropriate, include comparisons to the unmodified organism. For viruses and viral vectors, please also consider the information required in 14.1 above.	
14.3	**How could the environment be harmed from an unintentional release of the GMO(s) into the environment? Discuss the seriousness and likelihood of the potential harm.** This relates to the environmental impact of an unintentional release of a GMO from containment. If appropriate, include comparisons to the unmodified organism.	

14.4	**Do you propose to transport the GMO(s)? If so:** **i. What is the purpose of the transport (e.g. between certified facilities, or for import, supply, storage or disposal)?** ii. **How do you propose to contain the GMO(s) during transport?** iii. **How does the proposed transport impact on potential risks to people and the environment?** Note that 'transport of a GMO' is a dealing under the *Gene Technology Act 2000.* Contractors involved in transport of GMOs may be considered persons covered by a licence. Please provide details of any third party contractors that may be involved in transport of the GMOs, and the details of such transport. For example: • What GMOs will be transported by contractors, and to/from which locations? • What are the risks associated with transport of the GMOs? • What procedures would be used to inform contractors of: o the conditions of any licence that may be issued? o the risks associated with transport of the GMOs? • How would the proposed contractors be assessed as suitable to transport the GMOs? These details will facilitate an assessment of whether or not contractors involved in transport of the GMOs would be considered persons covered by a licence.	
14.5	**How will the GMO(s) be disposed of?** This includes arrangements for disposing of the carcasses of all animals inoculated with GMO(s), as well as liquid and solid waste from the dealings. If addressed previously please refer to the appropriate section. Note that 'disposal of a GMO' is a dealing under the *Gene Technology Act 2000.* Contractors involved in decontamination and/or disposal of GMOs may be considered persons covered by a licence. Please provide details of any third party contractors that may be involved in decontamination and/or disposal of the GMOs and the proposed method(s) of such decontamination and/or disposal. For example: • Will the GMOs be decontaminated in a certified facility prior to collection by waste contractors? If so, which staff will conduct the decontamination, and where? • What are the risks associated with decontamination and/or disposal of the GMOs? • If viable GMOs are to be handled by waste contractors, what procedures would be used to inform those contractors of: o the conditions of any licence that may be issued? o the risks associated with the GMOs? • How would the proposed contractors be assessed as suitable to perform decontamination and/or disposal of the GMOs? These details will facilitate an assessment of whether or not contractors involved with decontamination and/or disposal of the GMOs would be considered persons covered by a licence.	

14.6	**How do you propose to decontaminate equipment used during the proposed dealings in order to render any GMO(s) nonviable?** If addressed previously please refer to the appropriate section.	
14.7	**What are the steps in your contingency plan in case of an unintentional release of the GMO(s)?** Please note that this question refers to the unintentional release of the GMOs into the environment (for example, a spill outside a certified facility). In general, the steps must cover how: • the unintentional release will be contained and people protected; • the area and any people will be decontaminated; • the contaminated material will be disposed of; and • the incident will be reported. Also include here contingency plans to deal with the escape of any animals to be used during the proposed dealings. Note that it is required in the Act that the Regulator must be notified if there has been an unintentional release of the GMO from containment.	
14.8	**Are there any other actions and cautionary steps you will take to minimise risks posed by the proposed dealing(s)?** These refer to precautions that are over and above those outlined in any applicable certification guidelines.	
14.9	**What steps will you take to notify all persons covered by the licence of the licence conditions?**	

Part 15: Related authorisations or applications

Please provide details of any previous or current authorisations related to this application. This may include licences or NLRDs. Please also include a copy of the IBC assessment of any related NLRDs.

Reference number	Title of project	Date of application	Project supervisor

Part 16: References

Please provide copies (electronic or paper) of the citations included in the application.