Application for DNIR (storage)

For Storage of GMOs that do Not involve an Intentional Release of the GMO into the environment (contained dealings)

RESTRICTIONS ON THIS LICENCE

1) This licence is limited to:

- immediate and ongoing storage of the GMOs identified in the licence application and not other dealings, or disposal of them by autoclaving, incineration or any other method approved in writing by the Regulator; and
- transport of the GMOs between certified facilities and storage units identified in the notification and for disposal in accordance with the OGTR *Guidelines for the transport of GMOs* and for the purpose of storage.

2) This licence does not permit the storage of:

- GMOs used in conjunction with a whole plant or animal;
- GMOs that are for use in clinical trials with human beings; or
- more than 10 litres of GMO cultures.

3) Any GMOs that are stored outside certified facilities must be stored in accordance with the OGTR *Guidelines for Certification of facilities/ Physical Containment Requirements*.

4) In the event of an unintentional release of stored GMOs from containment, the clean up must be conducted in accordance with the procedure described in Part 5 of the notification.

Preliminary information

1. a) Applicant Organisation:_____

   b) Project Supervisor:_____

2. Do the GMOs stored relate to any previous NLRD or GMAC dealing?

   ☐ Yes ☐ No

   If yes, please provide NLRD or Gene Manipulation Advisory Committee (GMAC) number(s) here. _____

Time taken to complete this application: ☐

CCI Information

3. Are you applying for a declaration of Confidential Commercial Information (CCI)?

   ☐ Yes ☐ No

   If yes, have you attached an application for a declaration of CCI to the end of this DNIR licence application (after Part 13)?

   ☐ Yes ☐ No

   If the CCI is covered by previous CCI application(s), please provide the CCI application number(s) here. _____

Abbreviations

the Act	the *Gene Technology Act 2000* (Commonwealth)
CCI	Confidential Commercial Information
DIR	Dealings involving an Intentional Release of a GMO into the environment
DNIR	Dealings Not involving an Intentional Release of a GMO into the environment
GMAC	Genetic Manipulation Advisory Committee
GMO	genetically modified organism
IBC	Institutional Biosafety Committee
OGTR	Office of the Gene Technology Regulator
PC1, 2 *etc*	Physical Containment Level 1, 2 *etc*
the Regulations	the *Gene Technology Regulations 2001* (Commonwealth)
the Regulator	the Gene Technology Regulator

General information about applying for a DNIR licence

Providing information to the Office of the Gene Technology Regulator (OGTR)

Before issuing a licence for dealings involving a GMO, the Gene Technology Regulator (the Regulator) is required, under the Act, to assess the risks posed by the dealings, including any risks to the health and safety of people or to the environment.

The information you provide in your application is used to conduct a risk assessment and develop a risk management plan in regard to the proposed dealings. The resulting risk management plan will be the basis of the conditions in a licence if issued.

It is therefore important to provide information that is as comprehensive as existing scientific knowledge permits, and supported by whatever data are available to you.

The Regulator (or the Regulator's delegate) may require you to provide additional information and will notify you if this is required.

Accuracy of information

Please answer all questions that have not already been completed. Check carefully before you submit your application that all the information it contains is accurate. If the information you provide is incorrect or incomplete the Regulator's decision about this application may be delayed or the Regulator may not issue a licence.

The Act provides for penalties to a person who gives information to the Regulator that they know to be false or misleading.

Confidentiality

If you wish to make an application for a declaration that specifies information is Confidential Commercial Information (CCI) for the purposes of the Act, you must also complete the CCI application form available at www.ogtr.gov.au and place it at the end of this application (after Part 13).

Privacy

Any personal information is safeguarded by the *Privacy Act 1988*. This prevents the submitted personal information from being used for purposes other than assessing the licence application, or other circumstances specified by the *Gene Technology Act 2000* (Commonwealth). In certain circumstances information supplied during the course of an application for a licence may, according to their specific needs, be given to the following:

- an officer or employee of the Department of Health and Ageing;
- an officer or employee of a State government agency or organisation;
- Courts, Tribunals and/or other Commonwealth agencies where it is an obligation under law to provide it;
- law enforcement authorities; and
- the relevant Minister.

Information regarding applications received by the OGTR will also be published at www.ogtr.gov.au/gmorec/contained.htm. This is a public record and includes, for each DNIR application, the organisation name and State, project title, a brief description of the project and the status of the application.

Timeframes

The statutory time period for the Regulator to make a decision on a DNIR application is 90 working days. A licence is generally issued for a maximum of 5 years.

Application authorisation

Please ensure that if you are completing this application on behalf of the proposed licence holder, that you hold the proper authority to submit this application for the proposed licence holder.

Further information

Please contact the OGTR by:

Telephone: 1 800 181 030

E-mail: ogtr@health.gov.au

The *Handbook on the Regulation of Gene Technology in Australia - A User's Guide to the Gene Technology Act 2000 and related legislation* and other information are available at www.ogtr.gov.au.

The completed application can be lodged as follows:

1. Directly: Office of the Gene Technology Regulator
   Level 1, Pharmacy Guild House
   15 National Circuit, Barton ACT 2600

2. Mail: Office of the Gene Technology Regulator
   Commonwealth Department of Health and Ageing

MDP 54, PO Box 100
Woden ACT 2606

3. Fax: (02) 6271 4202 (the original to follow in the mail)

Please retain a copy of your completed application.

Acknowledgment of receipt

Once received, a storage DNIR number will be assigned to the application and the relevant IBC secretary will be informed. Please use this DNIR number to refer to any matters in regard to the application.

If you have not received a DNIR number within two weeks, please e-mail ogtr@health.gov.au or telephone 1 800 181 030.

Instructions on how to prepare this application

Please save a copy of this document on your own computer system.

Insert your answers either in the space provided or underneath each question replacing the explanatory information and/or examples. Only complete the questions that have not been completed

Part 1
This Part is to be completed by the Applicant organisation's representative

Part 2 to 5
These Parts are to be completed by the Project Supervisor. Please complete any questions that are applicable and have not already been completed.

Part 6
This Part is to be completed by the IBC for the proposed licence holder.

Part 7
This Part is to be completed by the Applicant Organisation's representative.

Part 8

This Part is for the required signatures from the:

- the Applicant Organisation's representative;
- Project Supervisor; and
- IBC chair.

Part 1: Proposed licence holder

Organisation name:	
Accreditation number:	

Details of the person the OGTR can contact regarding this application

Name:	
Position:	
Business telephone number:	
Mobile telephone number:	
Facsimile number:	
E-mail address:	
Street address:	
Postal address:	

Part 2: Project Supervisor

Project supervisor's name:	
Position within the organisation:	
Relevant qualifications:	
Relevant experience:	

Contact details of the Project Supervisor

Business telephone number:	
Mobile telephone number:	
Facsimile number:	
E-mail address:	
Postal address:	

Part 3: About the proposed dealings with the GMO or GMO(s)

To answer the questions in this Part, please firstly remove any explanatory text and then insert your answer directly under the question.

3.A What is the title of the dealing? (eg. storage of GMOs that are a licensed dealing).

3.B Briefly describe the project, including the purpose and aims of the proposed dealing.

Storage or disposal of GMOs that require a licence. The GMOs will be stored in certified facilities or in other restricted access areas (such as a locked freezer). The GMOs may be transported for disposal. Transport must be in accordance with the OGTR *Guidelines for the Transport of GMOs*. If any work with the GMOs is proposed, a separate licence application will be submitted.

Part 4: Description of the GMO

The information requested in Parts 4 to 8 is required to help identify any possible hazards associated with storing the GMO(s). Some questions in Parts 4 to 8 may also relate to risk assessment and risk management, which are addressed in Part 9.

In the previous section you will have generally described the GMO(s) within the context of your project.

In Part 4, a more specific description of the GMO(s) is required. This includes a description of all the GMO(s) to be stored, for example, bacteria used for sub-cloning steps, virus-infected tissue culture cell lines *etc*.

Please replace any explanatory text with your answers. Alternatively, you may choose to present this information in a table (refer to the examples in Table 1 at the end of Part 4). A blank table has also been provided at the end of this Part.

4.A What are the common and scientific names of the parent organism(s)?

The "parent organism" means the organism (or tissue derived from organisms) that is genetically modified.

4.B What vector(s) or methods were used for the transfer of genetic material?

4.C Were any of the host/vector systems that were used listed as a host/vector system for exempt dealings in Part 2 of Schedule 2 of the Gene Technology Regulations 2001 (the Regulations)?

In this case, "host" equates to "parent" as described in Part 4.A above.

4.D What is/are the modified trait(s)?

4.E What are the identities (or classes) of the gene(s) responsible for the modified trait?

In terms of identifying any possible hazards, the primary interests here are in the gene(s) or classes of genes under study.

The level of detail that is required is outlined in Table 1 at the end of Part 4.

4.F What is/are the biological source of the gene(s) responsible for the modified trait(s) isolated?

In regards to gene(s) commonly used as markers, for selection and/or any other routine procedures, please indicate the plasmid from which these gene(s) were derived. The level of detail that is required is outlined in Table 1 at the end of Part 4.

Table 1 - Examples of responses to Part 4: The description of the GMO(s)

The “parent organism” means the organism(s) (or tissue derived from organisms) that you propose to genetically modify and “host” equates to “parent”.

4	4.A		4.B	4.C	4.D	4.E and 4.F	4.G
GMO	**Common name of parent organism**	**Scientific name of parent organism**	**Vector(s) or method of transfer**	**Exempt Host/vector system?**	**Modified trait**	**Identity or class of gene(s) and biological source**	**Organisms or tissues to be used with the GMO(s)**
1	human cell line	293	transduction by recombinant retroviral vector pLXSN	no	resistance to neomycin	*neo* gene from pLXSN (Stratagene)	Not applicable
					expression of CD44 receptor	CD44 (transmembrane signalling molecule) gene from *homo sapiens*	
					fluorescence (expression of Green Fluorescent Protein or GFP)	*gfp* gene from *Aequorea victoria*	
2	mouse retroviral packaging cell line (amphotrophic)	PA317 mouse embryo fibroblast	$CaPO_4$ transfection of pLXSN	no	resistance to neomycin	*neo* gene from pLXSN (Stratagene)	Not applicable
					expression of CD44 receptor	CD44 (transmembrane signalling molecule) gene from *homo sapiens*	
					fluorescence (expression of GFP)	*gfp* gene from *Aequorea victoria*	

4	4.A		4.B	4.C	4.D	4.E and 4.F	4.G
GMO	**Common name of parent organism**	**Scientific name of parent organism**	**Vector(s) or method of transfer**	**Exempt Host/vector system?**	**Modified trait**	**Identity or class of gene(s) and biological source**	**Organisms or tissues to be used with the GMO(s)**
3	mouse retroviral packaging cell line (ecotropic)	Psi-2 mouse embryo fibroblast	$CaPO_4$ transfection of pLXSN	yes	resistance to neomycin	*neo* gene from pLXSN (Stratagene)	Not applicable
					expression of CD44 receptor)	CD44 (transmembrane signalling molecule) gene from *homo sapiens*	
					fluorescence (expression of GFP)	*gfp* gene from *Aequorea victoria*	
4	bacteria	*Escherichia coli*	pBR322 by electro-poration	yes	resistance to ampicillin	*amp* gene from pBR322	none
					uncharacterised	uncharacterised genes from *Mus musculus*	

The Table below can be used to enter your answers.

The “parent organism” means the organism(s) (or tissue derived from organisms) that you propose to genetically modify and “host” equates to “parent”.

4	4.A		4.B	4.C	4.D	4.E and 4.F	4.G
GMO	**Common name of parent organism**	**Scientific name of parent organism**	**Vector(s) or method of transfer**	**Exempt Host/vector system?**	**Modified trait**	**Identity or class of gene(s) and biological source**	**Organisms or tissues to be used with the GMO(s)**
1							Not applicable
2							Not applicable

Part 5: Risk assessment and management

Note: In the event of an unintentional release of the stored GMO(s) from containment, the spill must be contained and the area immediately decontaminated by means of 70-100% ethanol and/ or sodium hypochlorite (at least 1%) or other appropriate bactericidal or viricidal agent. Disposable equipment used for this procedure, such as paper towels, must be disposed of by autoclaving or incineration.

5.A What are the risks that could arise from the genetic modification, including occupational health and safety risk for people involved in the dealing?

5.B In regard to the health and safety of people and the environment, what are the possible hazard(s) and the likelihood and consequence of the hazard(s) occurring (*ie* the risk) from an unintentional release of the GMO(s) into the environment?

5.C Have applications (whether successful or unsuccessful) been previously made under the Act, or to the Genetic Manipulation Advisory Committee (GMAC), in relation to a proposed dealings with the GMO?

- Reference Number
- Date of Application
- Project supervisor

This information can be tabulated if there are multiple applications as indicated in Table 2.

Table 2

Reference number	Date of application	Project supervisor

5.D Do you propose to store a GMO outside a certified facility?

Yes ☐

No ☐

5.E Will GMOs stored outside certified facilities be stored in locked storage units in restricted access areas?

Yes ☐

No ☐

Certified Facility details

Name of facility:	
Facility address:	
Physical containment level:	
Date of certification (if applicable):	
Certification number (if applicable):	
Date of most recent inspection:	
Who undertook the inspection:	

(Any GMOs that are stored outside certified facilities must be stored in accordance with the OGTR *Guidelines for Certification of facilities/ Physical Containment Requirements*).

If you are using more than one facility you may tabulate the information as in Table 3 below.

Table 3 Facility details

Information required	**Facility 1**	**Facility 2**
Name of facility		
Facility type		
Physical containment level		
Date of certification		
Certification number		
Date of most recent inspection		
Facility address details		

Part 6: IBC evaluation of this application

Note that a separate *IBC Evaluation Form* is not required if Part 11 is completed.

If a risk assessment has been carried out please provide a copy after Part 11.

Insert any additional information under the question to be answered.

IBC Details

Name of IBC:	
Name of IBC Chairperson:	
Business telephone number:	
Mobile telephone number:	
Facsimile number:	
E-mail address:	

Name of IBC Secretary:	
Business telephone number:	
Mobile telephone number:	
Facsimile number:	
E-mail address:	

IBC evaluation of application

6.A Date of IBC evaluation:_____

6.B 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

6.C Has the information contained in the Preliminary Information and Parts 1–10 been checked by the IBC and found to be complete? If no, please indicate why. (Please note that if the applicant intends to use facilities at another organisation that the appropriate IBCs must all agree to this).

☐ Yes ☐ No

6.D Does the IBC consider that the personnel to be involved in the proposed dealings with the GMO(s) have adequate training and experience for the task? If no, please indicate why.

☐ Yes ☐ No

Part 7: Suitability of the proposed licence holder

7.A Has a copy of the applicant's statutory annual report been submitted to the Regulator?

☐ Yes ☐ No

If yes, please provide the application number with which these documents were submitted.

Application number:_____

If no, please either provide these documents at the end of Part 12 or provide an Internet address below for access to such documents.

Internet address:_____

Please note that "annual report" does not refer to the *Accredited Organisation Annual Report to the Gene Technology Regulator*.

7.B Have there been any relevant convictions of the proposed licence holder and/or the Project Supervisor?

Proposed Licence Holder ☐ Yes ☐ No

Project Supervisor ☐ Yes ☐ No

According to the Act, "***relevant conviction*** *means a conviction for an offence against 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, if:*

(a) the offence was committed within the period of 10 years immediately before the making of the application for the licence; and

(b) the offence was punishable on conviction by a fine of $5,000 or more, or by a term of imprisonment of one year or more."

If this applies, please provide details at the end of Part 12.

7.C Has there been any failure by the proposed licence holder to comply with:

(a) a provision of the Act or Regulations; or
(b) a condition of a licence or permit (particularly if resulting in a revocation or suspension) held under a law relating to the health and safety of people and the environment?

☐ Yes ☐ No

If yes, please provide details at the end of Part 12.

7.D Have there been any failures by the proposed licence holder to comply with an advice to proceed issued by the GMAC?

☐ Yes ☐ No

If yes, please provide details at the end of Part 12.

7.E Is there any other information you can provide to the Regulator that is relevant to making a decision on this application?

☐ Yes ☐ No

If yes, please provide details at the end of Part 12.

Part 8: Signatures

I declare that to the best of my knowledge, having made reasonable inquiries, the information herein is true and correct. I understand that providing misleading information to the OGTR, deliberately or otherwise, is an offence under Commonwealth law.

Applicant organisation's representative

Signature: _____Date: _____

Printed Name: _____

Project Supervisor

Signature: _____Date: _____

Printed Name: _____

IBC Chair

Signature: _____Date: _____

Printed Name: _____

(Please note that the Office can not accept photocopies of signatures)