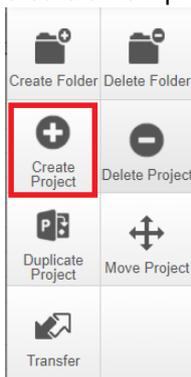


NAVIGATING iRECS

New Application - Gene Technology/Regulated Biological Materials

1. To create a new project (application), click on **Create Project** on the left-hand navigation panel.



2. Enter your **Project Title** (i.e. research project name) and select **Regulated Biological Materials Application**, click **Create**.

The image shows a 'Create Project' dialog box. It has a title bar with a close button (X). Below the title bar, there are two input fields. The first is labeled 'Project Title* (Max 200 characters)' and contains the text 'Project CRISPR-Cas9'. The second is labeled 'Form*' and is a dropdown menu with 'Regulated Biological Materials Application' selected. At the bottom right of the dialog, there are two buttons: 'Create' (highlighted with a red box) and 'Close'.

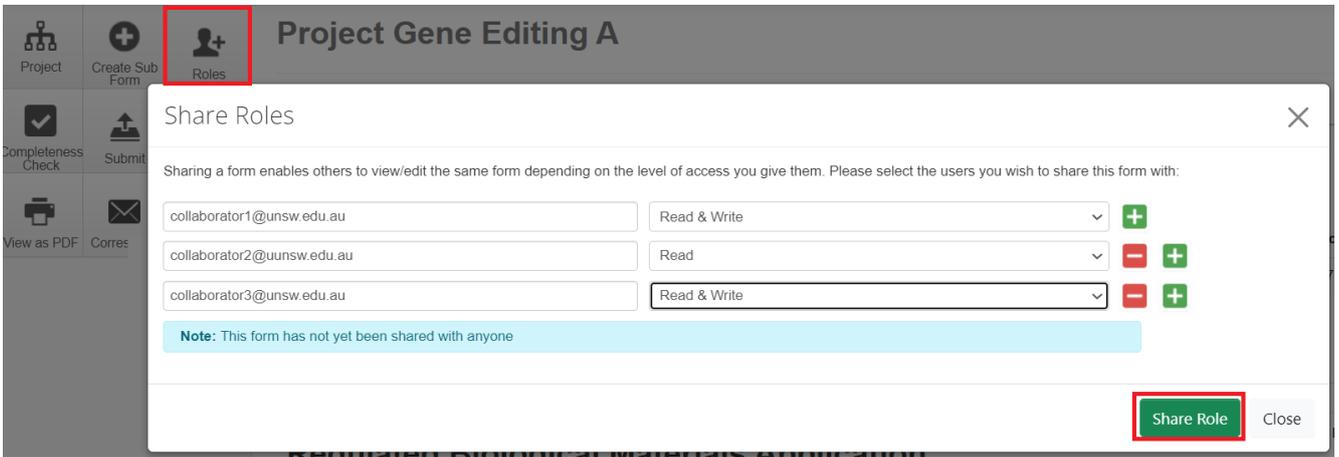
3. You will arrive at the following page:

The image shows a web page titled 'Project Gene Editing A' with the number '0415' in the top right corner. On the left, there is a navigation panel with icons for 'Project', 'Create Sub Form', 'Roles', 'Completeness Check', 'Submit', 'Refresh', 'View as PDF', and 'Correspond'. The main content area shows a 'Project Tree' with a tree view containing 'Project Gene Editing A' and 'Regulated Biological Materials Application'. Below the tree is a table with columns: 'Action Required on Form', 'Status', 'Review Reference', 'Application Type', and 'Date Modified'. The table has one row with values: 'Yes', 'Not Submitted', 'N/A', 'N/A', and '22/11/2022 15:39'. Below the table are tabs for 'Navigation', 'Documents', 'Signatures', 'Collaborators', 'Submissions', 'Correspondence', and 'History'. The 'Regulated Biological Materials Application' section is expanded, showing a 'Section' list on the left and a 'Questions' list on the right. The 'Section' list includes 'Before you start', 'New Application / Modification Request', 'Assessment of Dealings', 'Project Information', 'Attachments', 'Declaration', and 'Submission'. The 'Questions' list includes 'Before you start', 'New Application / Modification Request', 'Assessment of Dealings', 'General Details', 'Project Details', 'Project Personnel', 'Attachments', 'Declaration', and 'Submission'. There is a checkbox for 'Show Inactive Sections' in the top right of this section.

4. **Optional – Invite Collaborators:** At this stage, you can invite collaborators to complete the application form by clicking on **Roles**. A pop-up will appear, enter each collaborator's **name/email address**, and their **access type** ('Read', 'Read & Write' OR 'Read, Write & Submit'). Click on the **+** button to add another collaborator to the list, repeat the process until all collaborators are added. Click **Share Role** to complete the process.

Note: Only the **Project Lead/Supervisor** should be granted '**Read, Write & Submit**' access.

Note: Ideally, the **Project Lead/Supervisor** should be the one creating and submitting each **iRECS** application, as they are responsible for what is declared in each application. If you are filling in the **iRECS** application on behalf of a **Project Lead/Supervisor**, you need to transfer the record to the **Project Lead/Supervisor** to complete the necessary declarations and review the application before submission. See "**Transferring iRECS Projects**" for transfer instructions.



5. To commence your application process, click on the **Before you start** hyperlink.

Regulated Biological Materials Application

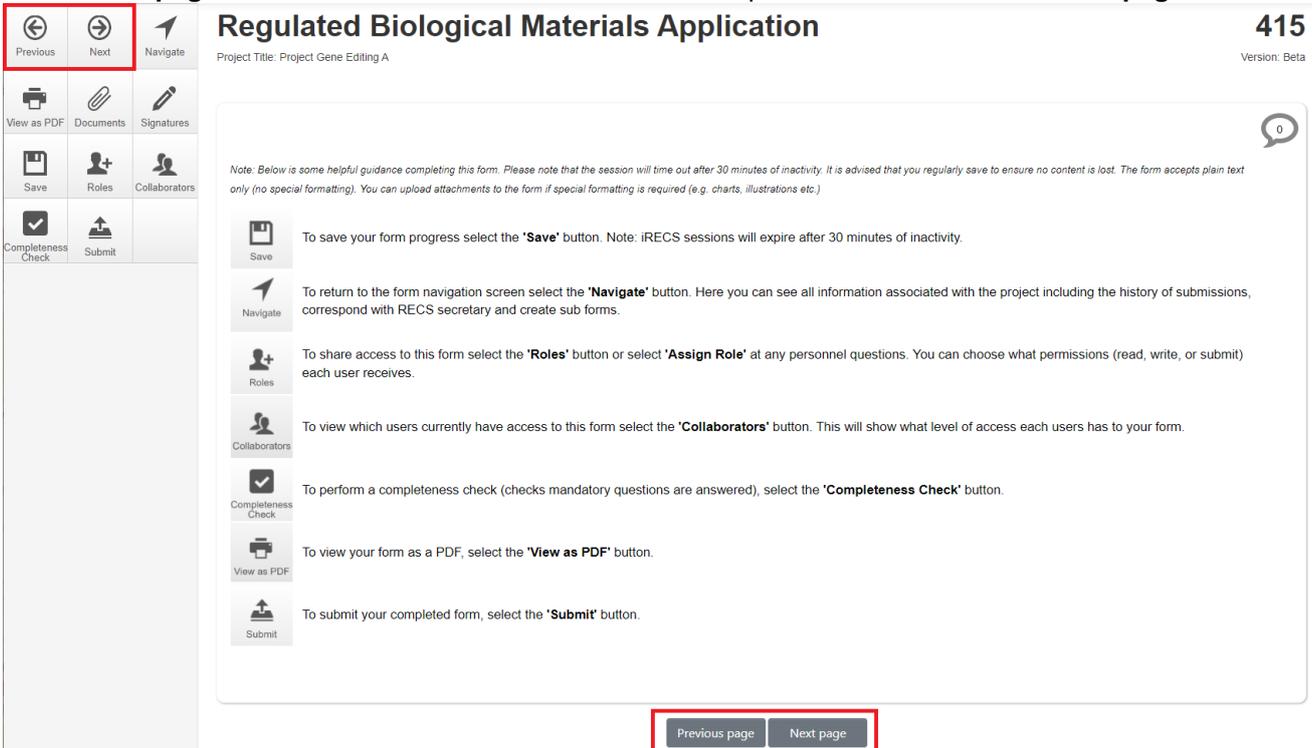
Section

- Before you start
- New Application / Modification Request
- Assessment of Dealings
- Project Information
- Attachments
- Declaration
- Submission

Questions

- Before you start**
- New Application / Modification Request
- Assessment of Dealings
- General Details Project Details Project Personnel
- Attachments
- Declaration
- Submission

6. Note the different functionalities on the page. You can navigate to the next page by clicking on **Next page/Next** or **Previous page/Previous** buttons at the bottom or left-hand panel of the screen. Click **Next page/Next**.



7. Select **New Application** and click **Next Page**.

New Application / Modification Request 0

If this is the first time you are completing this form or if it has not been reviewed and approved please select 'New Application'. To modify the application after approval select 'Modification' and provide a brief summary of the requested modifications.

New Application

Modification

[Previous page](#) [Next page](#)

8. Select the appropriate **Assessment of Dealings** for your research project, then click **Next Page**.

Regulated Biological Materials Application 415

Project Title: Project Gene Editing A Version: Beta

Assessment of Dealings 0

Research involving NLRDs
Any research involving an NLRD with a GMO requires approval from the UNSW Gene Technology Research Committee (GTRC). A written Record of Assessment from the UNSW GTRC will be provided to the Project Supervisor once the NLRD Project Application has been approved by the Committee. Work on the project may then commence.

Research involving Exempt Dealings
Research involving an Exempt dealing with a GMO does not require approval from the GTRC. However the Project Supervisor must notify the GTRC of the proposed research via a Notification of Exempt Dealing and a GTRC Identification Number must be issued before work can commence.

Research involving both NLRD and Exempt Dealings
Where the research involves both NLRD and Exempt dealings, it will be treated as NLRD.

Risk Group 3 Pathogen Approval
Application for access to UNSW PC3 space and equipment.

How to identify the type of dealing / approval type:
For definitions and classification of dealings see: <https://research.unsw.edu.au/what-type-classification-and-approval-my-dealing>

Where an application contains both NLRD and Exempt, it will be treated as an NLRD application.

Please indicate dealings covered by this form:

- Exempt
- NLRD
- NLRD and Exempt
- Risk Group 3 Pathogen Approval

[Previous page](#) [Next page](#)

9. For projects involving **Exempt** dealings, you (i.e. Project Lead/Supervisor) are required to complete the following declaration. Check the **Accept** checkbox and click **Next Page**.

Note: If you are filling in the iRECS application on behalf of a Project Lead/Supervisor, you should advise the Project Supervisor to complete this section upon transferring the record to him/her for review and then submission. Note also that a Project Supervisor is ultimately responsible for what is declared in each application. See the “Transferring iRECS Projects” guide for transfer instructions.

Notification of Exempt Dealing 0

The Office of Gene Technology Research (OGTR) defines Exempt dealings as a category of dealings with GMOs that have been assessed over time as posing a very low risk (i.e. contained research involving very well understood organisms and processes for creating and studying GMOs). Exempt dealings are described in Parts 1 & 2 of Schedule 2 of the (amended) Gene Technology Regulations 2001.

Research involving an Exempt dealing with a GMO does not require approval from the UNSW GTRC. However the Project Supervisor must notify the GTRC of the proposed research via a Notification of Exempt Dealing and a GTRC Identification Number must be issued before work can commence.

It is a legislative requirement that Exempt dealings must not involve an intentional release of a GMO into the environment.

The Project Supervisor agrees that:

- There will be no intentional release of GMOs into the environment.
- Any spills outside of the facility or loss/suspected loss of GMOs including down the laboratory sink will be reported to the GTRC Support Officer, email: genetechnology@unsw.edu.au, phone: 02 9385 7244 as soon as possible after the event in order that the OGTR can be informed.

Accept

Previous page Next page

10. Complete all relevant fields of the **General Details** section of the web form. Click **Next page** once complete.
Tip: Save your progress by clicking on the “**Save**” button on the left-hand panel to save your progress and/or complete your application next time.

General Details

Is this project a:

11. Complete all relevant fields of the **Project Details** section of the web form. Click **Next page** once complete.
Tip: Save your progress by clicking on the “**Save**” button on the left-hand panel to save your progress and/or complete your application next time.

Project Details

Project Title

Project Gene Editing A

12. For the **Project Personnel** section, specify the **Project Supervisor/Lead** by entering the **supervisor's name** into the **search box**, the supervisor's details will then auto-populate in the details fields. Specify the supervisor's **Organisation Details** from the drop-down list. Click **Assign Role**.

Project Supervisor Details

A Project Supervisor **cannot** be a student. If the project is to be undertaken by an Honours, Masters or PhD student, then the supervisor must be the Project Supervisor. All correspondence will be addressed to the Project Supervisor.

Note: Below is some helpful guidance on completing the personnel section of the form. Use the 'Search User' field to prefill iRECS users information.

Assign Role

After specifying the contact details. Select 'Assign Role' to share the form. This enables others to view/edit the same form depending on the level of access you give them.

J G (z @unsw.edu.au)

Title Sci

First Name J

Surname G

Organisation Details Please Select...

Phone 5

zID z

Email z @unsw.

Training Record 130016, 90020, ACECR

Assign Role

13. Next, enter the **name of each researcher and/or student** involved in the project into the **search box**, the project personnel details will then auto-populate in the details fields. Click **Assign Role** to share the form with said personnel.

Note: You will not be prompted to complete this section if you declare **Exempt** in the Assessment of Dealings section.

Tip: Save your progress by clicking on the "Save" button on the left-hand panel to save your progress and/or complete your application next time.

Project Personnel

Note: Below is some helpful guidance on completing the personnel section of the form. Use the 'Search User' field to prefill iRECS users information.

Assign Role

After specifying the contact details. Select 'Assign Role' to share the form. This enables others to view/edit the same form depending on the level of access you give them.

S S (z @unsw.edu.au)

Title Dr

First Name S

Surname S

Email z @unsw.edu.au

zID z

Training Record HSEGTC

Assign Role

14. Click **Add Another** and repeat the above process until you have all project personnel added.

Add Another

15. Depending on the **Assessment of Dealings** you indicated, you may be required to specify additional personnel details. E.g.:

- If you declare *NLRD* or *NLRD and Exempt*, specify all the classes of people who will be involved during the life of the project.

Classes of people who may be involved in the future (tick as many as required)

Note: *The Project Supervisor is responsible for ensuring that all project personnel receive appropriate training prior to joining the project. Training requirement details can be found on the [Gene Technology website](#).*

- Other Technical Research assistants Visiting academics
- Honours students Postdocs PhD students

- If you declare *Risk Group 3 Pathogen Approval*, you are required to specify:

PC3 facility supervisor

PC3 facility supervisor must have maintained PC3 level C training category for at least 6 months

16. Click **Next page** once complete.

17. Complete the **GMO Description and Genetics** section for **each GMO** that your project will deal with.

Tip: See the "[GMO Description and Genetics Example](#)" section below for tips on how to complete this section.

Tip: Save your progress by clicking on the "Save" button on the left-hand panel to save your progress and/or complete your application next time.

GMO Description and Genetics

Use the section below to list all GMOs (being used or generated) individually. Specify host organism, vectors, genes (identity and function of nucleic acid and organism of origin), method of transfer and modified trait (eg antibiotic resistance).

18. To add another GMO item, click **Add Another** or **Duplicate** (duplicate the previous item). Repeat the process until you have all GMOs added. Click **Next page** once complete.

19. For **Attachments**, click on **Upload Document** to attach any additional **supporting documents** for your project. Click **Next page** once complete.

Attachments

Attach any additional supporting documents here.

20. For the **Declaration** section, enter the name of the **relevant HoS/Centre** into the **search box**, the HoS/Centre details will then auto-populate in the details fields. **Do not click Assign Role (unless the HoS is a collaborator in the research project)**. The nominated HoS will be notified upon submission of your application. Click **Next**.

Declaration

Head of School/Centre

Please nominate your head of school/centre to be notified upon approval of this application.

Title

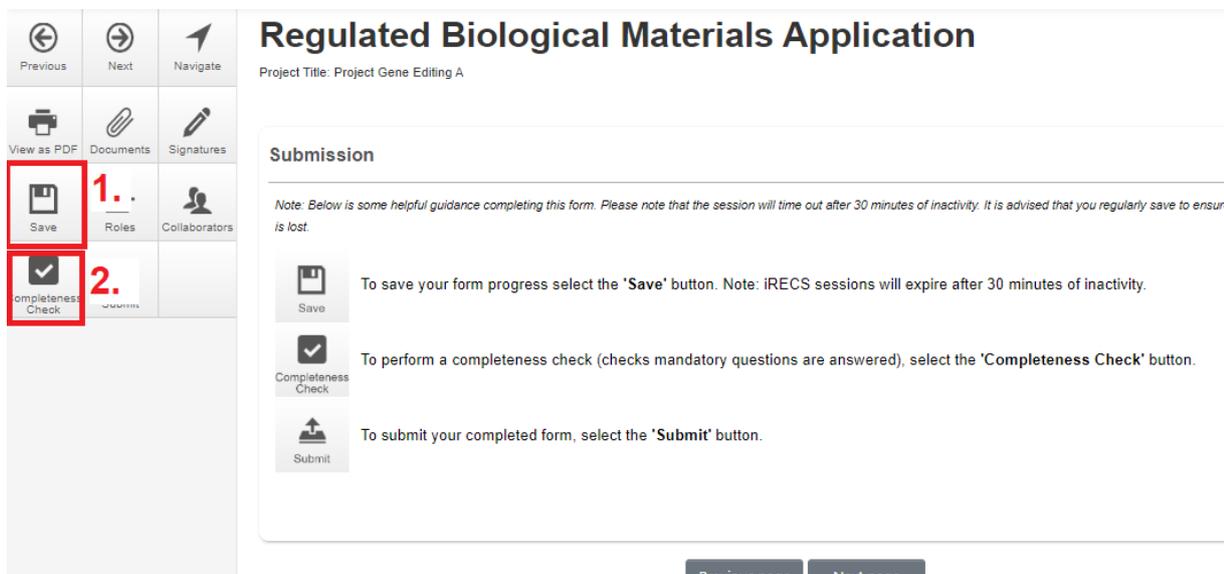
First Name

Surname

Email

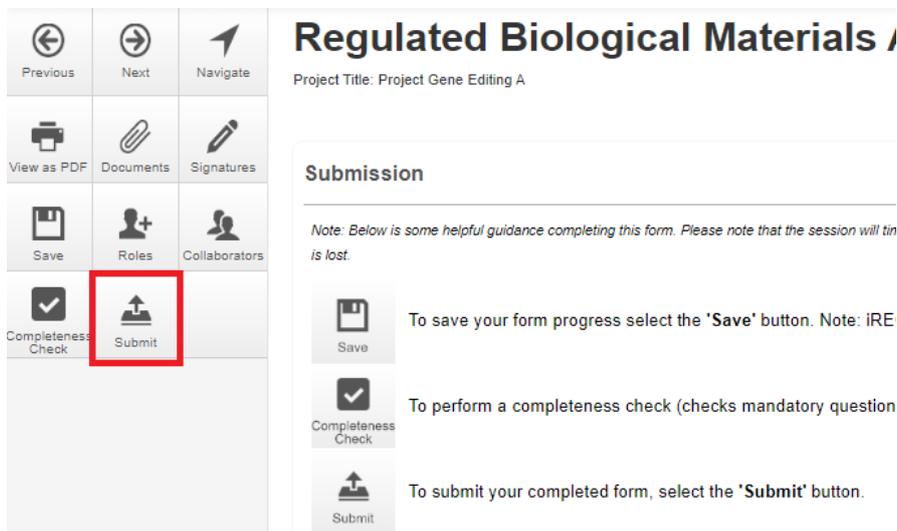
21. You have now completed your application. To save your application, click **Save**, then click the **Completeness Check** button to ensure all sections have been completed.

Note: If you are filling in the iRECS application on behalf of a Project Lead/Supervisor, you need to transfer the record to the Project Lead/Supervisor at this stage to complete the necessary declarations, review and then submission. A Project Supervisor is ultimately responsible for what is declared in each submitted application. See “Transferring Records” transfer instructions.

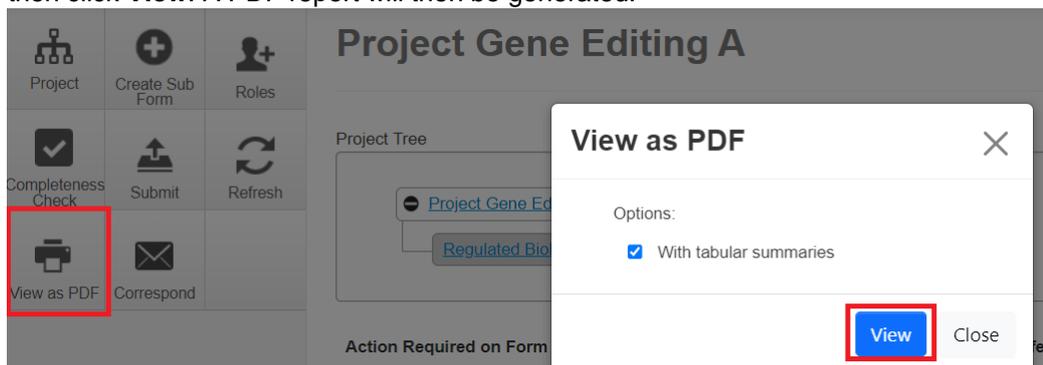


22. Should the completeness check indicate that your application is complete, click **Submit** to submit your application.

Note: If you are filling in the iRECS application on behalf of a Project Lead/Supervisor, you need to transfer the record to the Project Lead/Supervisor at this stage to complete the necessary declarations, review and then submission. A Project Supervisor is ultimately responsible for what is declared in each submitted application. See “Transferring Records” transfer instructions.



23. **Optional:** You can download a copy of the completed application (you can also do this pre-submission) by clicking on the **View as PDF** button. A pop-up will appear, **check/uncheck** the **With tabular summaries** option, then click **View**. A PDF report will then be generated.



GMO Description and Genetics Example

The following is an example of how you can fill in the GMO Description and Genetics section of your Gene Technology/Regulated Biological Materials application.

GMO No	Common Name	Scientific Name	Vectors	Method of Transfer	Identities	Functionalities	Organism of Origin	Phenotype	Classification
1	Human amphotropic retroviral packaging cell line	Homo sapiens	Replication defective retroviral vectors derived from Moloney Murine Leukaemia Virus that has viral genes (gag, pol and env) deleted	The packaging cells will be transfected with retroviral vectors using lipofectamine	Characterized non-toxic genes derived from human, or mouse that promote proliferation and/or tumorigenesis, including the growth factors VEGF and FGF. Amphotropic retroviral packaging cell line, Phoenix A. This packaging cell line harbours 2 plasmids encoding retroviral helper genes that enable packaging of retroviral vectors able to transduce human cells.	Drug resistance genes derived from bacteria that confer resistance to neomycin or puromycin	Human, Bacteria and Mouse	The transfected packaging cells will: Produce retrovirus that is able to infect human cells, but unable to replicate. May have enhanced proliferation and have properties of malignant cells Be resistant to the antibiotics neomycin and puromycin	NLRD 2.1 (I)(i)(ii)(iii)(A)
2	Murine embryonic fibroblasts (MEFs) from PTEN knock-out mice	Mus musculus	Non-conjugative plasmid vector encoding neomycin resistance gene derived from pBR322.	The gene knock out was previously performed by others.	Neomycin resistance gene derived from bacteria.	Drug resistance genes derived from bacteria that confer resistance to neomycin	Mouse and Bacteria	The MEFs are resistant to neomycin (geneticin). They exhibit properties of cancerous cells, including improved survival and proliferation.	Exempt Type 4
3	Transgenic C57/BL6 mouse (Mus musculus) carrying a c-kit transgene under control of the promoter of the immunoglobulin heavy chain	Mus musculus	Non-conjugative plasmid vector derived from pBR322	The mice were previously generated by transfection of embryonic stem cells with a non-conjugative plasmid	Human c-kit oncogene and bacterial neomycin resistance gene	Overexpression of the oncogene of the c-kit transgene and drug resistance to neomycin	Human and Bacteria	Expression of c-kit renders the mice susceptible to development of leukaemia. The mice are resistant to the antibiotic Neomycin (Geneticin).	NLRD 1.1 (a)
4	E. coli bacterial strains – BMH 71-18 mutS, JM 109, DH5α.	Escherichia coli	Non-conjugative plasmid encoding replication defective retroviral vector derived from Moloney Murine Leukaemia virus	E. coli will be transformed with the plasmid using heat shock and calcium chloride treatment.	The plasmid vector is driven by a promoter derived from cytomegalovirus and encodes (i) neomycin and (ii) ampicillin resistance genes derived from bacteria, as well as (iii) the human glucocorticoid receptor in wild-type and mutant forms	Expression of neomycin and ampicillin Expression of human glucocorticoid	Human and bacteria	Transformed bacteria will have altered protein expression and be resistant to ampicillin and neomycin	Exempt Type 4

FURTHER SUPPORT

- If you have any iRECS login or technical issues, please contact UNSW IT Services at itservicecentre@unsw.edu.au or (02) 9385 1333.
- For any queries, regarding the iRECS Human Ethics, Animal Ethics Gene Technology or Radiation Safety application approval and/or review process, please contact:
 - Human Ethics: humanethics@unsw.edu.au
 - Animal Ethics: animaethics@unsw.edu.au
 - Gene Technology: genetechnology@unsw.edu.au
 - Radiation Safety: radiationsafety@unsw.edu.au