

Reviewers: How to Review an Application

Step 1: Log into GSafe

You can log into GSafe from the Health, Safety & Wellbeing page <https://www.griffith.edu.au/health-safety-wellbeing> by selecting the link at the 'Access GSafe desktop edition >' button.

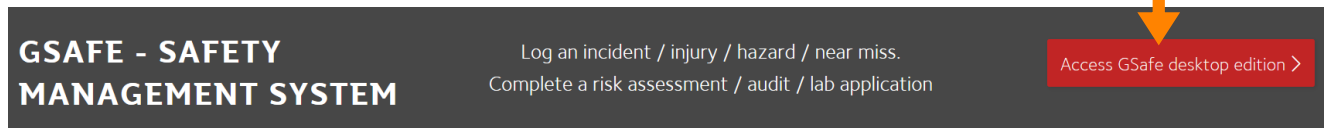


Figure 1

Alternatively, you can follow the link from a GSafe email notification direct to the application (providing you are logged into the Griffith system).

Step 2: Access the Activity Register

Open the activity register by selecting the underlined text (Activity Register) adjacent to the red GRIDD icon (Figure 2). The Activity Register will open with existing Activities displayed in the Register.



Figure 2

Step 3: Opening and Viewing the Application

Navigate to the application in the register and open it by clicking anywhere on the line where the application appears. The application will open and can be viewed by opening each tab to reveal the information contained within.

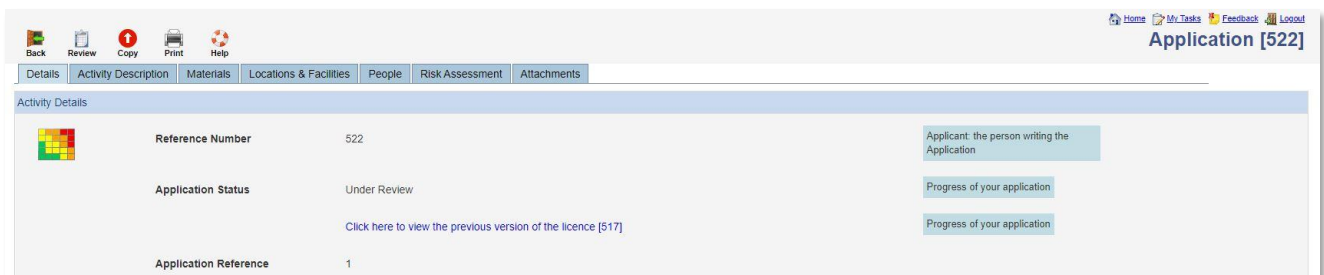


Figure 3

It is important to note that the 'Materials' and 'Locations' tabs may appear to have blank records when first viewed. The information for these tabs must be revealed by clicking the 'Display Materials' and the 'Display Locations' buttons, respectively (Figure 4 & 5).



Figure 4

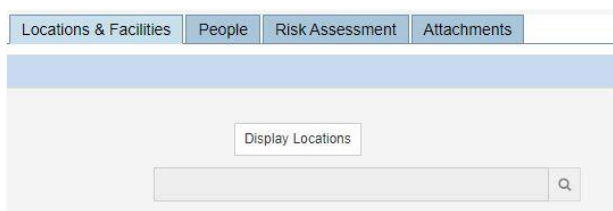


Figure 5

This will populate the tab with the records for the application and they can be reviewed. Once displayed, records will remain displayed if you navigate away from the tab and return. You will only have to click the 'Display' button if you close and reopen the application.

Step 4: Reviewing the Application Information

It is recommended to review the application content by working through each tab systematically. The tabs are arranged from left to right with the most critical and relevant information appearing on the first few tabs.

Details Tab

Contains mandatory fields including the application reference, title and dealing type/category.

Activity Description Tab

The project description and experimental procedures are listed here and can be reviewed and assessed against the selected dealing type to ensure the Regulatory requirements for the application are met. Regulatory information for each Section, Part and Item of the Regulations is given next to the checkbox for selection to save from having to refer to the OGTR Regulations document directly (Figure 6). Other information such as precautions for handling, GMO disposal and transport procedures, and Import information is provided by the applicant in this section as well.

Type of Exempt Dealing

In this section please indicate the type of Exempt Dealing you wish to conduct, selecting from the categories in Schedule 2, Part 1, Items (2, 3, 3A, 4, 5) of the OGTR Gene Technology Regulations 2001. Schedule 2, Part 2 of the same Regulations contains a list of Exempt Host/Vector systems.

Schedule 2, Part 1, Item 2 ☐ A dealing with a genetically modified *Caenorhabditis elegans*, unless: (a) An advantage is conferred on the animal by the genetic modification; OR (b) As a result of the genetic modification, the animal is capable of secreting or producing an infectious agent.

Schedule 2, Part 1, Item 3 ☐ Any dealing with an animal into which genetically modified somatic cells have been introduced, if: (a) The somatic cells are not capable of giving rise to infectious agents as a result of the genetic modification; AND (b) The animal is not infected with a virus that is capable of recombining with the genetically modified nucleic acid in the somatic cells.

Schedule 2, Part 1, Item 3A ☐ A dealing with an animal whose somatic cells have been genetically modified in vivo by a replication defective viral vector, if: (a) The in vivo modification occurred as part of a previous dealing; AND (b) The replication defective viral vector is no longer in the animal; AND (c) No germ line cells have been genetically modified; AND (d) The somatic cells cannot give rise to infectious agents as a result of the genetic modification; AND (e) The animal is not infected with a virus that can recombine with the genetically modified nucleic acid in the somatic cells of the animal.

Schedule 2, Part 1, Item 4 ☐ You must select both Sub-items 1 and 2 to demonstrate compliance with all conditions for this type of Exempt Dealing.

☒ Sub-item (1): Subject to sub-item (2), a dealing involving a host/vector system mentioned in Part 2 of this Schedule and producing no more than 25 litres of GMO culture in each vessel containing the resultant culture.

☒ Sub-item (2): The donor nucleic acid: (a) Must meet either of the following requirements: (i) It must not be derived from organisms implicated in, or with a history of causing, disease in otherwise healthy: (A) Human beings, OR (B) Animals; OR (C) Plants; OR (D) Fungi; (ii) It must be characterised and the information derived from its characterisation show that it is unlikely to increase the capacity of the host or vector to cause harm; Example Donor nucleic acid would not comply with subparagraph (ii) if its characterisation shows that, in relation to the capacity of the host or vector to cause harm, it: (a) Provides an advantage, or (b) Adds a potential host species or mode of transmission; OR (c) Increases its virulence, pathogenicity or transmissibility; AND (b) Must not code for a toxin with an LD50 of less than 100µg/kg; AND (c) Must not code for a toxin with an LD50 of 100µg/kg or more, if the intention is to express the toxin at high levels; AND, (d) Must not be uncharacterised nucleic acid from a toxin-producing organism; AND (e) if the donor nucleic acid includes a viral sequence - cannot give rise to infectious agents when introduced into any potential host species, without additional non-host genes or gene products that: (i) are not available in the host cell into which the nucleic acid is introduced as part of the dealing; and (ii) will not become available during the dealing; and (f) if the donor nucleic acid includes a viral sequence - cannot restore replication competence to the vector.

Figure 6

Materials Tab

Click the 'Display Materials' button to reveal the materials list (Figure 7), then select the ☒ to view the information for the selected material.

Selected Materials

E. coli	Scientific Name: Escherichia coli (K12 derivatives including BL21) Material Type: ED Material	☒ ☐ ☐
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Figure 7

Locations & Facilities

Click the 'Display Locations' button to reveal the list of locations where the proposed activity will take place. Each Location may have a different role in the project such as 'Main Dealing Location', or 'Storage Location' etc. The locations will often be added as a 'Suite' or collection of rooms under the one certification and each of the rooms under the suite will populate on the list individually as well. Individual rooms can be added by the applicant as well so it is important to check each entry on the list. Certification information for each room will be listed and the reviewer can confirm that required certifications for the proposed activity are held and current.

People

Participating persons for the activity will be shown along with their role and status of training certifications. Each person's training and experience should be appropriate for their role.

Risk Assessment

Risk assessments that have been associated with this activity are listed here. The risk assessment can be opened by selecting the  next to the listing. It is important to check that the risk assessment is relevant to the proposed activity and covers all aspects of the risks that may be associated with the activity. On the first page of the risk assessment the applicant may have included attachments such as SOP's as evidence to support administrative controls.

Attachments

Contains any other relevant documentation to the application. Responses to reviewer feedback may sometimes be provided by the applicant here as an attachment.

Step 5: Provide Review Comments

Once the application has been thoroughly reviewed, press the 'Review' button (**Figure 8**) to open the Review Application window (**Figure 9**). Feedback from the review can be provided for the applicant in the 'Feedback' field. Press the  button to save the feedback if you wish to return to the application to continue the review and provide more feedback later.

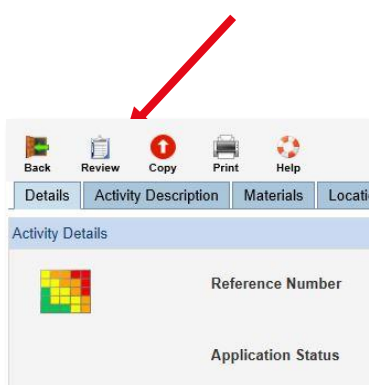


Figure 8

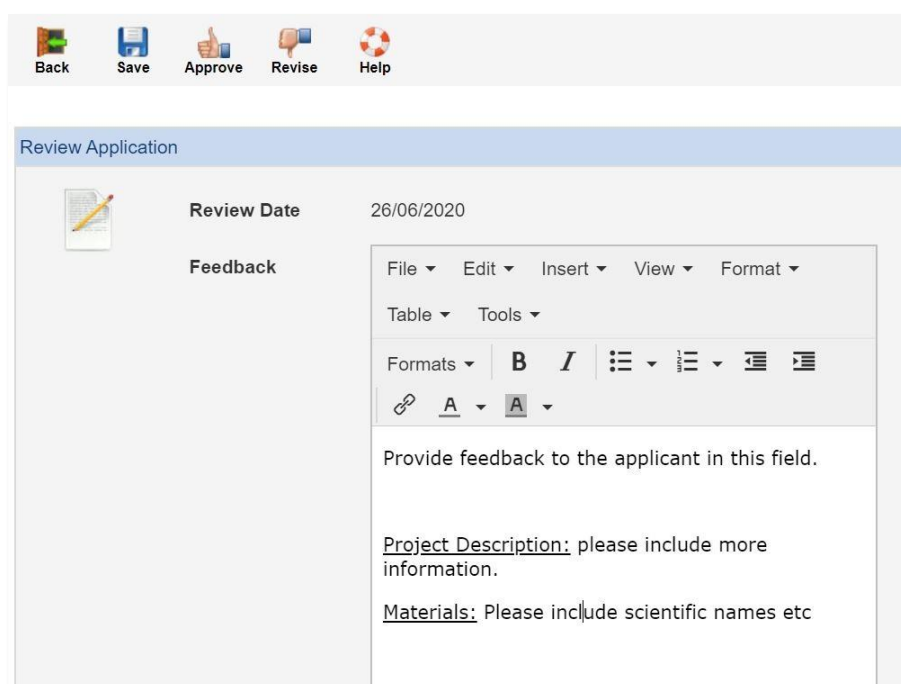


Figure 9

Step 6: Provide a Recommendation

Once all feedback has been provided and the review is complete a recommendation is required from the reviewer to either **Approve** or **Revise**. Approval can still be given where small errors exist such as typographical and grammatical errors. Revision should be recommended where significant changes or further information are required to ensure the application meets regulatory requirements. Select the 'Thumbs Up' to approve or 'Thumbs Down' (**Figure 10**) to recommend revision. A warning will appear to ask for confirmation before final submission – click 'Ok' to submit the response and then select the 'Back' buttons to return to the application and then the Applications Register or select home or logout from the top right of the screen and close the browser.

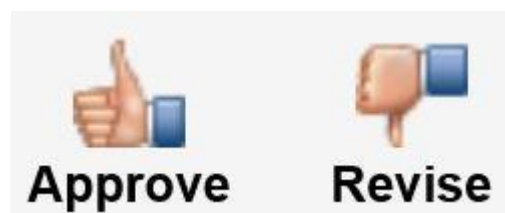


Figure 10

If you have any questions regarding this process please contact the HS&W Biosafety team at safety@griffith.edu.au