Ethics Review Manager (ERM) is used at Monash University for Gene Technology, Human Ethics, and Animal Ethics applications. ERM can be accessed on the following link: https://ethicsapps.monash.edu/

- Log in using your Monash email address and password. If you have problems logging in, you may need to clear your cache - please find instructions for your browser on the following link: clear your cache
- You will receive email alerts when action is required from donotreply@infonetica.net – ensure these emails are not filtered to a ‘junk folder’ in your inbox.

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If you can see the following red banner across the top of your project screen, the Chief Investigator (Project Owner) must click Update. The ‘submit’ button will not appear if the form needs to be updated. An update alert in a yellow banner is not mandatory and no functions are blocked.

**Warning:** The project owner must update your project in order to submit this form Update

### 1. Submitting an Application

#### Step 1. Click Create Project

1. Click Create Project
2. Enter the project title and select the relevant form from the dropdown list then click Create

#### Step 2. Enter the project title and select the relevant form from the dropdown list then click Create

<table>
<thead>
<tr>
<th>Form Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Animal Ethics Application Form</td>
<td>Applications to MARP, SBS, MIPS and MUM AECs</td>
</tr>
<tr>
<td>Animal Ethics Notification</td>
<td>Register a project that already has approval from another AEC</td>
</tr>
<tr>
<td>Gene Technology Application Form</td>
<td>Applications to Monash Institutional Biosafety Committee (MUIBC)</td>
</tr>
<tr>
<td>Human Ethics Application Form</td>
<td>Applications to Monash Human Research Ethics Committee (MUHREC)</td>
</tr>
<tr>
<td>Human Ethics Other HREC</td>
<td>Register a project that already has approval from another HREC</td>
</tr>
<tr>
<td>SPHPM Self Audit Form</td>
<td>Only complete if you have received a request to do so from SPHPM</td>
</tr>
</tbody>
</table>
Step 3. The project homepage will now appear. Complete all sections of the form listed under the ‘Navigation’ tab. Animal Ethics users also need to complete species information under the ‘Animal Ethics’ tab.

- For guidance on specific questions, click on the information icon on the right-hand side.

- Work through the form using the Previous and Next buttons in the left-hand action panel.

- Click Navigate to return to the project homepage.

- Click Completeness Check to ensure you have completed all mandatory questions. Please ensure the correct CI is listed before submission (refer to Section 2).

- To submit an application for review, click Submit. Then click Submit again in the subsequent pop up screen.

- All investigators listed on the application will receive an email receipt upon submission.

2. Listing Personnel

The Chief Investigator (CI) details will be auto-populated from the profile of the person who has created the application – if this is not the CI, the application will need to be transferred to the correct person prior to submission. Please refer to Section 5. Transfer an Application.

To add other Monash investigators and/or students:

Step 1. Search for the person in the ‘search user bar’ beneath the relevant subheading, and select them from the drop-down list.

Step 2. Double click to add their details to the contact block. The information is retrieved from the Monash University Identity Management System and cannot be edited.

- If the investigator’s name is not found using the search function, they need to log in and out of ERM to activate their profile – they will then appear in the search list.

- Click add another to add another investigator beneath the same subheading – ensure you use the new search user bar.

- External (non-Monash) investigators cannot be searched for in the Monash directory and must be added manually beneath the relevant subheading.

Listing an investigator on an application does not give them automatic access to the application in ERM. You must also share the application and give all Monash investigators ‘read’ access, please refer to Section 7. Share an Application.
3. Removing Personnel

If your project has been approved, you will need to submit an amendment to remove investigators. See Section 13 Submitting an Amendment, for instructions on how to initiate an amendment. Once a project is unlocked you can remove investigators by clicking ‘remove’ beneath the relevant person you wish to remove.

For mandatory roles, e.g. Deputy CI, Person Responsible for Animal Care, you cannot remove the person listed. Instead you will need to use the ‘Search User’ bar to enter the name of the person who will be taking on the role. Once selected, this person’s details will overwrite the details of the original investigator listed in the contact block.

If the person you are trying to remove is the only person listed in the section i.e. if there is only one student listed, and you are trying to remove this person, you will not see the remove button. Instead you’ll need to untick the relevant tick box above to remove the section from the form.

You cannot remove the Chief Investigator, see Section 6 Transferring an Application for instructions on how to change the CI.

After amending personnel, you should review the Collaborators tab to ensure that only the required people have access to your project. You may need to remove access to any investigators no longer involved in the project. See Section 7 Sharing an Application for instructions on editing access permissions.

4. Adding Comments

Whilst editing an application, investigators can add comments to specific questions within the application (e.g. a student wanting to check their response to a question with the CI). These comments will only be visible to other investigators with access to the application (they will not be visible to Committee Members or the Ethics/Compliance Office).

Step 1. To add a comment, click the Comment bubble to the right of the relevant question.

Step 2. Click + Add Comment and type the comment you wish to make then click save.

- The comment icon next to the relevant question will show that a comment has been added. Click on the icon to view/edit the comments.

- You can view a list of all comments by clicking Comments in the left-hand action panel.
5. Organising Your Work Area

Folders can be created to organise your Work Area (ERM homepage).

**Step 1.** Click Create Folder

**Step 2.** Enter a name for the folder.

**Step 3.** Click Create.

**Step 4.** To move projects into the folder, drag them from the Project List.

6. Transferring an Application (Changing the CI)

The Project Owner (Chief Investigator) must be the lead Monash Supervisor with overall responsibility of the project. This cannot be a student.

Project ownership can be transferred; however, this process removes the current CI from the project. If this person is still involved with the project, it is advised that they add themselves to the project as a co-investigator/student before transferring the project to the new CI. After acceptance of the transfer, the new CI can then give appropriate ‘share’ access (See Section 7) to the previous CI as necessary.

**Step 1.** Starting in your Work Area (ERM homepage), click Transfer in the left-hand action panel.

**Step 2.** In the email address field, enter the email address of the new Chief Investigator. **Note:** This must be a Monash email address.

**Step 3.** Select the relevant project from the list.
Step 4. Click **Transfer** to complete the action. The new Chief Investigator will receive an email to inform them of the transfer request.

**To Accept or Reject a Transfer**
Click on the link in the transfer request email, or begin from your Work Area.

**Step 1.** Click **Transfers**

**Step 2.** Click **View Project** to review the project details.

**Step 3.** In the left-hand action panel, click **Accept Transfer** or **Reject Transfer**. If the transfer is accepted, the project will now appear with the new Chief Investigator listed beneath ‘Owner’ in the project list.

**Step 4.** The Ethics/Compliance Office will be in touch if an amendment is required.

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### 7. Sharing an Application with Monash Collaborators

Listing an investigator in the relevant personnel section of the form does not automatically give them access to read the application. Applications must be ‘shared’ with all listed investigators. You can also assign permissions to edit an application and to submit amendments or reports.

**Step 1.** Open the application you wish to share. Click **Roles** in the action panel.

**Step 2.** Enter the email address of the person you would like to share the project with. **Note:** This must be a Monash email address.

**Step 3.** Select the relevant level of permission for this person then click **Share Role**.

- **Read Only** – view application (but not edit)
- **Full Access** – excluding ability to submit
- **Full Access** – including ability to submit

**Step 4.** Click the **Plus** icon to share the project with more collaborators.

**Note:** You cannot share individual sub-forms with collaborators, you can only share the entire project using the Role function located at the main form level.
View Applications that have been shared with you

Projects already shared with you will be listed in the projects list in your Work Area (ERM Homepage). The Owner listed is the Chief Investigator. Projects can also be viewed in the Shared folder.

If a project was shared with you by mistake, or if you no longer require access to the project, you can reject the project in your Shared folder by clicking Reject on the right-hand side of the relevant project. Please note this does not remove you as an investigator from a project. If you want to be removed as an investigator, please contact the CI and ask that they submit an amendment to remove you.

Manage Collaborator Permissions

The Chief Investigator (and investigators with Full Access – including the ability to submit), can edit collaborator access.

**Step 1.** Open the relevant application, then click Roles. You must have the main form selected in order to see this button. Collaborators who have been assigned roles will be listed here.

**Step 2.** Click Remove to remove a specific role that has been assigned to a collaborator, or, if the collaborator has multiple roles and is therefore listed multiple times, you can click Remove All Permissions for this person. If a collaborator is listed multiple times, the role with the highest level of access will apply. You cannot edit an existing role, but you can remove roles and re-assign a new role if required.

8. Printing an Application

To print an application form (without supporting documents), open the relevant application; click Print in the left-hand action panel.

To print an application form and all supporting documents, open the relevant application; click the Documents tab, then click Download all as Pdf.
9. Corresponding with the Ethics/Compliance Office

Step 1. Open the relevant application; click **Correspond** in the left-hand action panel.

Step 2. Enter a message for the Ethics/Compliance Office.

Step 3. To attach a file, click **Choose Files** and follow the prompts. You can attach multiple files if they are stored in the same folder.

Step 4. Click **Send**. The system automatically generates a notification to the Ethics/Compliance Office.

Step 5. To check the Correspondence trail, click the **Correspondence** tab.

10. Responding to Reviewer Comments

Following review, you will receive an email if the Committee requires further information. Reviewer comments will be sent to you via ERM, and you are required to address them directly within the application form.

Step 1. After opening the project, click **Reviewer Comments** in the left-hand side action panel. The red number will indicate how many comments you have been sent.

Step 2. Click on the first comment in the list to navigate to the relevant question in the form. You can read the reviewer comment again from the relevant section of the form by clicking on the ‘Reviewer Comments’ bubble to the right of the question. The left bubble displays reviewer comments; the right bubble displays comments between investigators.

Step 3. Amend the relevant sections of the form as required. **Do not** make any other changes than those requested by the reviewers.

Step 4. Changes to documents should be made using track changes and uploaded in the relevant sections of the form with a new date and version leaving previous versions in place.

Step 5. Once complete, please click **Submit**, then click **Submit** again in the subsequent pop up screen. All investigators listed on the application will receive an email receipt upon submission.
11. Duplicating an Application

Do not use this function to submit an amendment — instead refer to instructions in Section 13.

You are able to duplicate the content of an existing application into a new application. This function is useful if you have multiple projects with similar content, or if you need to replace an expired application.

Note that you can only duplicate a project if you are the project owner.

**Step 1.** In your Work Area (ERM homepage) click Duplicate Project.

**Step 2.** Enter the new project title

**Step 3.** Edit and submit the new application — ensure that all information duplicated is relevant to the new application. Do not upload legacy files or previously approved amendments — if these are still relevant, the content should be added into your responses to the form questions so that your new application can be reviewed as a standalone application.

All form content will be duplicated into the new project except for any attached documents which will need to be uploaded manually. Animal Ethics users will also need to manually update the Animal Ethics tab since species information cannot be duplicated.

12. Deleting / Withdrawing an Application

If you have started but **NOT SUBMITTED** an application, you can delete it if you no longer require it:

**Step 1.** Starting in your Work Area (ERM homepage), click Delete Project in the left-hand action panel

**Step 2.** Select the project you wish to delete from the drop-down list, click Delete

If you no longer require an application which you have **SUBMITTED** but is not yet approved, you are able to withdraw it. If you wish to make a change to your submitted application, please contact the relevant Ethics/Compliance Office for advice. Please do not withdraw the application.

**Step 1.** Click on the relevant project to open it.

**Step 2.** Click Withdraw in the left-hand action panel
13. Submitting an Amendment

Amendments must be submitted and approved by the relevant Committee prior to implementation.

Amendments are made directly to the application form within ERM. Amendments can be made by the CI, or by anyone who has been granted edit and submit access by the CI (See Section 7 – Sharing a Project).

Step 1. Open the project you wish to amend.

Step 2. Send a correspondence message requesting that the project is unlocked for an amendment and include a brief summary of the amendments you wish to make (See Section 9 – Correspond with the Ethics/Compliance Office).

Step 3. You will receive an email from donotreply@infonetica.net when your project is unlocked by the office, enabling you to make amendments to the application. This email will contain instructions for submitting the amendment.

Step 4. Make your required amendments to the relevant sections of the form. Changes to documents should be made using track changes, and uploaded in the relevant sections of the form with a new date and version.

Step 5. Upload an amendment summary document outlining the changes made in the Supporting Documents section of the form (in Human Ethics this is Section K1, in Animal Ethics - Section G).

To submit an amendment on an ‘Other HREC/MOU’ registration, please upload the application for amendments and the amendment approval certificate issued by the primary HREC in the Documentation Section (5.5) of the application.

Gene Technology users should include a brief summary of what the amendment entails at the bottom of the Project Summary (5. Description of dealing) e.g. “Amendment May 2018: This amendment involves the addition of a new GM mouse line (please see 6a).”

Step 6. Click Submit to send your amendment for review. Then click Submit again in the subsequent pop up screen. All investigators listed on the application will receive an email receipt upon submission.

14. Submitting a Report

Where applicable, annual reports, final reports and incidents or adverse events are submitted in ERM as a ‘sub-form’ of the main application. All sub-forms linked to a project are listed beneath the main application form in the ‘Project Tree’.

Step 1. Starting in your Work Area (ERM Homepage), open the project you wish to submit a report for.

Note – you will only be able to view projects for which you are the CI, or projects which have been shared with you. Contact the CI if you need access to a project.

Step 2. Click Create Sub Form on the Actions tool bar on the left-hand side of the screen.

Note - If you cannot see the ‘create sub-form’ button, check your access permissions under the Collaborators tab – if it does not say ‘create all sub-forms’ next to your name, the CI will need to complete the report.

Step 3. Select the relevant report from the dropdown list. Complete the form, click Submit, then click Submit again in the subsequent pop up screen. All investigators listed on the application will receive an email receipt upon submission. It is the CI’s responsibility to share the application with other investigators as required see Section 7, Share a Project.
15. Registering a Project – Other HREC

Monash University researchers who have obtained ethical approval for a project from another Human Research Ethics Committee (HREC) are required to register their project with MUHREC if the research involves any of the following:

- Funds being administered by Monash University
- Students undertaking research or placement for their degree at the other institution (e.g. a hospital)
- The project will contribute to their research output such as publications, conference presentations

These projects will not be subject to a full review with MUHREC, but will be checked for governance matters that may need to be flagged to other areas of the university.

To Register a Project

Registrations should be created by the Chief Investigator (Monash supervisor). The CI can then add students and/or other investigators, share the project with them and assign their permissions as required so that they can view and work on the application.

**Step 1.** Starting in your Work Area (ERM homepage), click Create Project and select Human Ethics – Other HREC form.

**Step 2.** Begin at Section 1: Application Type and work through the form using Previous and Next in the left-hand action panel, or click Navigate to return to the project homepage.

- For guidance listing Monash personnel – Please refer to Section 2
- Upload a copy of the original application that was submitted to the primary human research ethics committee, as well as a copy of the approval certificate. Note that these documents must be in English.
- Prior to submitting an application, please ensure that you transfer, share and add collaborators to the application as required. Please refer to Section 6, Transfer a Project and Section 7. Share a Project.

**Step 3.** Once complete, please click Submit, then click Submit again in the subsequent pop up screen. All investigators listed on the application will receive an email receipt upon submission.

16. Useful Templates

Click Help > Templates for useful documents including amendment summary templates, monitoring sheets, explanatory statement and consent form templates.
17. Ethics/Compliance Office Contact Information

Technical Support (for technical issues with ERM)
  mro-infonetica_support@monash.edu

Human Ethics
  muhrec@monash.edu +61 3 990 52052
  Further Information

Gene Technology and Biosecurity
  gene.technology@monash.edu +61 3 990 24951
  Further Information

Animal Ethics
  MARP - animal.ethics@monash.edu
    MARP-1 +61 3 990 55121
    MARP-2 +61 3 990 24735
    MARP-3 +61 3 990 54518
  MIPS – mips.aec@monash.edu
  SBS - biol.aec.secretary@monash.edu +61 3 990 55678
  Further Information