

## So, you think you want to amend your approved RM<sup>1</sup> human research project

After receiving the written approval from the RMIT HREC or an RMIT CHEAN to begin a research project, you must follow the project procedures and use only the versions of the recruitment materials, consent and assent forms and study instruments as approved and on file with the RMIT Office of Research Ethics and Integrity. However, if you find that you need to make changes to the study, you may do so by requesting an amendment through the RMIT Research Ethics Platform.

REP can be accessed via the **My Ethics** tab in the [Researcher Portal](#) or directly via this link: <https://researchethics.rmit.edu.au/>. REP is part of the RMIT single sign on and you can log in using your RMIT e-number or student ID/RMIT email address and password.

**The amendment must be approved by the appropriate review body before you initiate the change.**

Amendments that require approval include, but are not limited to, extensions, changes in Principal Investigator (PI), inclusion/exclusion criteria for participants, sites of study, recruitment strategy, consent and authorisation process, participant information and consent form, questions on survey/interview/focus groups, testing procedures, confidentiality measures, or safeguards for participants. Conducting a study with unapproved procedures invalidates the approval status. If you're not sure if what you are doing falls into this category, Research Governance and Ethics Coordinators (RGE Coordinators) are available to help. Simply email [humanethics@rmit.edu.au](mailto:humanethics@rmit.edu.au).

### How long will the process take?

It is the Project Owner's responsibility to allow enough time for the ethical review process. Please note that RM applications approved prior to the implementation of REP only appear in the Project Owner's work area. The Project Owner/Chief Investigator listed on the original application will either need to submit the amendment RM request or share the application to allow a co-investigator to submit the amendment RM. Requests for amendment should be submitted well in advance of the changes being implemented. All requests are reviewed in the order in which they are received.

Factors that may have an impact on the timeframe for review include:

- the completeness and quality of the amendment request
- review category of the project, e.g., negligible versus greater than low risk review
- the nature of the amendment to be made
  - o administrative amendments can typically be reviewed and approved by the RGE Coordinators

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<sup>1</sup> Human Research Project approved before 27 February 2020.

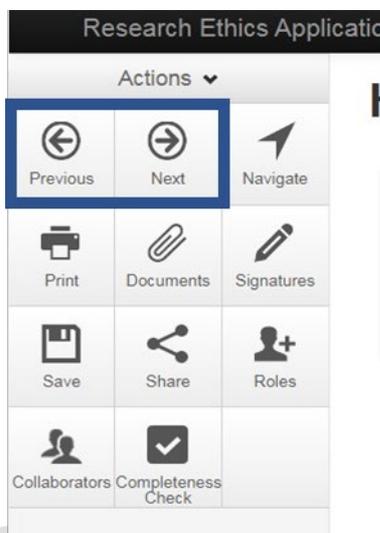
- amendments involving research purpose, design and methodology, recruitment and participants, data and confidentiality, or a change in risk level will need to be reviewed by the relevant HREC or CHEAN and will take longer
- total number of requests currently under active review by the CHEAN or HREC
- response time by the Project Owner to provide requested information
- potential wait for external documents or letters of permission from related items

We recommend you start your request for amendment at least **six (6) weeks** before you need to make the change in your project. This will allow time for all steps in this process including the governance review, discussions and any necessary modifications, and then ethical review. This document will help you submit a request for amendment that should meet the requirements of the RMIT Human Research Ethics Procedures.

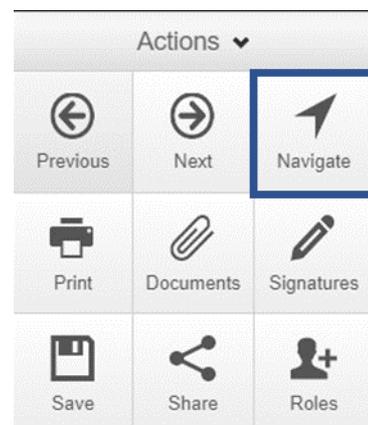
Directions for completing the request for amendment RM are imbedded within the form. This guide is designed to sit alongside REP as you familiarise yourself with the ethics process here at RMIT. More detailed REP instructions are also available in the help section of REP along with other guidance notes on other types of applications including registration of other HREC ethical approvals, animal ethics approvals, amendments, and progress reports.

RGE Coordinators are available to assist researchers in answering questions on completing the request for amendment RM and about relevant guidelines. Simply email [humanethics@rmit.edu.au](mailto:humanethics@rmit.edu.au) and someone will get back to you!

#### A quick refresher on REP basics:



Within the **Actions Panel** on the left-hand side of the screen, use the **Previous** and **Next** buttons to move between sections within the form or use **Navigate** to return to the form overview.



**After a period of inactivity, you will be logged out of the system. Please ensure you save your work regularly using the Save button on the Action Panel to avoid losing any unsaved changes.**

Please note that all questions marked with a **red asterisk (\*)** are **mandatory** and must be answered. If you think a question does not apply, write *N/A*. No response areas should be blank.

**Let's Get Started!****Creating a new request for amendment RM**

**Step 1. From your work area, select the project you wish to amend and on the **Actions Panel**, click **Create Sub-form**.**

**Step 2. Select **Human Research Ethics Amendment RM Request** from the dropdown list and click **Create**.**

The screenshot shows a web browser window with the URL <https://researchethics.rmit.edu.au/Project/Index/6183>. The page title is 'Research Ethics Applications' and the user is 'DR Melina Vidoni'. A 'Create Sub-form' dialog box is open, displaying a dropdown menu with the following options: 'Please Select...', 'Please Select...', 'Human Ethics Annual Report RM', 'Human Ethics Final Report RM', 'Human Research Ethics Amendment RM' (highlighted), 'Human Research Ethics Annual Report RM', and 'Human Research Ethics Final Report RM'. The background shows the 'Human Research Ethics RM' application form with a 'Start' button.

**Step 3. You are now in the application form. To begin, click the **Start** section.**

The screenshot shows the 'Human Research Ethics Amendment RM' application form. The 'Start' section is highlighted, and the 'Start' button is visible. The form includes sections for 'Section' and 'Questions'. The 'Section' section lists: 'Start', '1. Project Details', '2. Amendment Request', and '3. Declaration'. The 'Questions' section lists: 'Start', 'Project Details', 'Amendment Request', and 'Declaration'. The background shows the 'Human Research Ethics RM' application form with a 'Start' button.

## Start

Because your project was migrated to REP from the system RMIT used previously, you will need to download the amendment request form associated with those older projects. That download is available from the **Introduction** page once you have clicked on **Start**.

Research Ethics Platform | Research Ethics Applications | <https://researchethics.rmit.edu.au/Project/Page/1679/11522>

Research Ethics Applications | Work Area | Contacts | Help | DR Melina Vidoni

### Human Research Ethics Amendment RM

22460  
Version: 0

**Note:** There is a newer version of the project. [Update](#)

#### Introduction

This form is to request changes to an Human Research Ethics application approved prior to the introduction of the online Research Ethics Platform in March 2020. Completion of this form is required for project amendments, personnel changes or an extension.

Please download and complete the [amendment request](#) and attach completed form to the Amendment Details section of this form.

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You will attach the completed form later in the submission process.

## Section 1: Project Details

The good news is – this section will auto populate from your original project application!

## Section 2: Request Details

Research Ethics Platform | Research Ethics Applications | <https://researchethics.rmit.edu.au/Project/Page/4904/11522>

Research Ethics Applications | Work Area | Contacts | Help | DR Melina Vidoni

### Human Research Ethics Amendment RM

22460  
Version: 1.0.10

#### 2.1 Request Details

**Please attach completed amendment request form \***

[Upload Document](#)

**Please attach copies of any documents that will require updating due to the proposed amendments.**

[Upload Document](#)

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**Please upload the completed amendment request form.**

This is the amendment request form you downloaded at the Start section. The form is very straight forward. We do want to highlight a couple of the sections to help you get through the process easily:

**1.6 Provide a summary of the original project.**

**Assume when preparing your summary that the reader does not have a copy of the original application.**

The data migration process to REP provided a number of PDF documents but older projects do not have the flexibility built in as those that were entered directly into REP. The RGE Coordinators can access the older documents as needed but if you provide a well written project summary, this is likely to lessen the need for that and may shorten the amount of time needed to conduct the review. You can usually find this on your original application in your project file.

**3.1.2 List those aspects of the study you would like to amend. Make sure to include a rationale and background for each of the amendments. Cite any references where appropriate.**

Basic administrative items (research team, protocol timeframes) are covered in other questions. In this question you want to tell us about any changes to the research methodology, the recruitment protocol, the informed consent process, the process for collecting human research data or human bio-specimen data, the research data management protocol, or any other changes not otherwise listed on the form.

Use short, clear sentences. Using bullets or timetables for multiple visits or procedures.

- Amendment 1: Change to the research methodology ...
- Amendment 2: Addition of an assent document for children ...
- Amendment 3: Change to location due to COVID-19 restrictions ...

By separating each amendment, it is very clear to the reviewer that there are three changes and in specific sections of the original project, providing an understanding of the ethical principles apply.

**Remember: Writing in Lay Language:** Ethical review submissions including associated documents should be written in lay language ([National Statement 5.2.7](#)) – Think of it as writing for the average adult population. Avoid technical or professional language such as may be used in grant submissions or with peers.

**3.1.3 Explain how the requested amendments will alter the original approved project. Remember to revise any documents associated with the approved application that will be altered if the amendment is approved**

Again, using bullets to relate the changes and their impacts back to each amendment will make the review go smoothly and show how you have considered the ethical principles in relation to those changes.

***If a question does not apply to your request for amendment, please indicate with "N/A."***

**Please attach copies of any documents that will require updating due to the proposed amendments.**

This may include the Participant Information and Consent Form, recruitment materials, surveys, or other research instruments.

To upload a document from your device, click on the blue 'Upload Document' button.

Click the **Browse** button to locate the relevant file. Assign a version date and number for each document you upload and use consistent file naming conventions. And then click **Upload**.

### Section 3: Declaration

Complete the declarations checklist on REP and validate the form.

When you have answered all required questions and uploaded all required supporting documents, you need to click the **Completeness Check** button in the **Actions panel**.

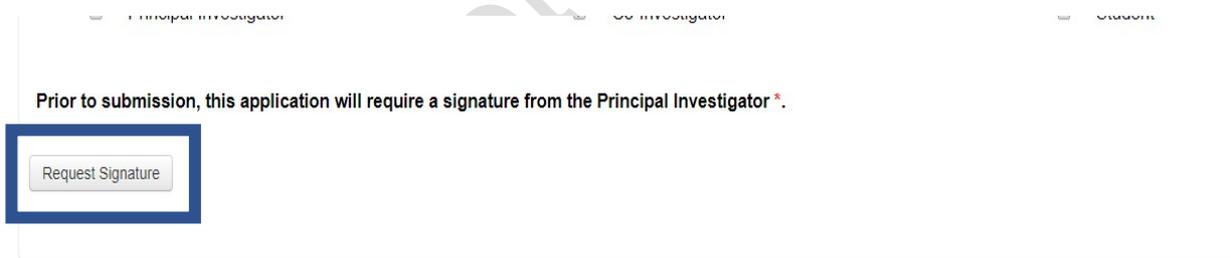
The system will check that all mandatory questions have been addressed. A list of mandatory questions which have not been addressed will be displayed. Clicking the question within the dialog box will bring you to the relevant question within the form.

#### Submitting the Form

##### *Obtaining Form Signatures*

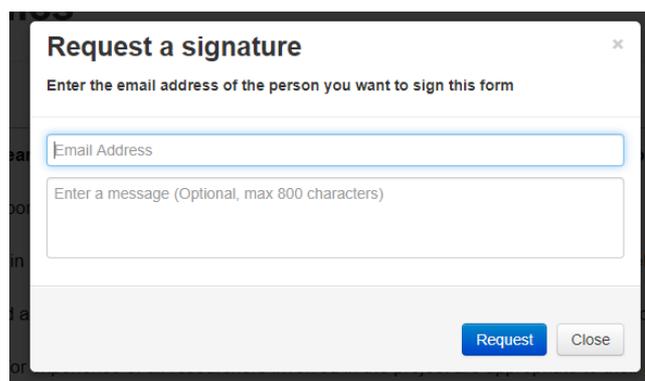
If you are submitting the form as either a co-investigator or student on a project, you will be required to obtain the signature of the PI.

To obtain a signature, click on the 'Request Signature' button



The screenshot shows a form submission interface with three tabs: 'Principal Investigator', 'Co-Investigator', and 'Student'. Below the tabs, a message states: 'Prior to submission, this application will require a signature from the Principal Investigator \*'. A button labeled 'Request Signature' is highlighted with a blue border.

Enter the email address of the PI and an optional message in the text boxes within the dialog box and click **Request**.



The screenshot shows a dialog box titled 'Request a signature'. It contains the following elements:

- Header: 'Request a signature' with a close button (X).
- Instruction: 'Enter the email address of the person you want to sign this form'.
- Text input field: 'Email Address'.
- Text area: 'Enter a message (Optional, max 800 characters)'.
- Buttons: 'Request' (blue) and 'Close' (grey).

The PI will be notified of the request, and once signed you will be notified via email that the form has been signed and is ready for submission.

### Form Submission

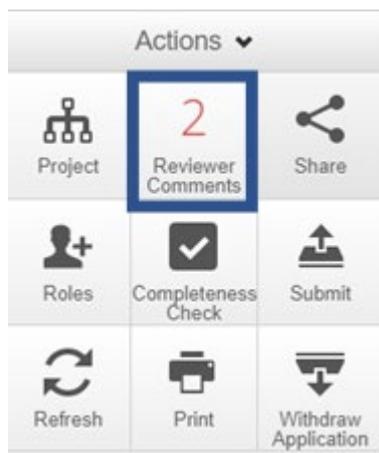
Once all mandatory questions have been completed, the request for amendment can be submitted for review by clicking the **Submit** button in the **Action panel**. Then click **Submit** again in the subsequent pop-up screen to confirm.

### What Happens Next?

#### Governance Review

Within three business days of submitting a completed request for amendment RM on REP, an RGE Coordinator will begin a Research Governance Review.

Once your form has undergone a governance review to ensure that it is complete, you may be notified via email that further information is needed or some changes are required. The form is unlocked for you to make revisions and the status of the form updated to 'Revision Required.'



To view the comments made during governance review, click the **Review Comments** button on the **Actions panel**.

This will display a list of comments made against the current submission of the form. Click each comment to be taken to the corresponding question.

The question requiring clarification/amendment will be highlighted in red.

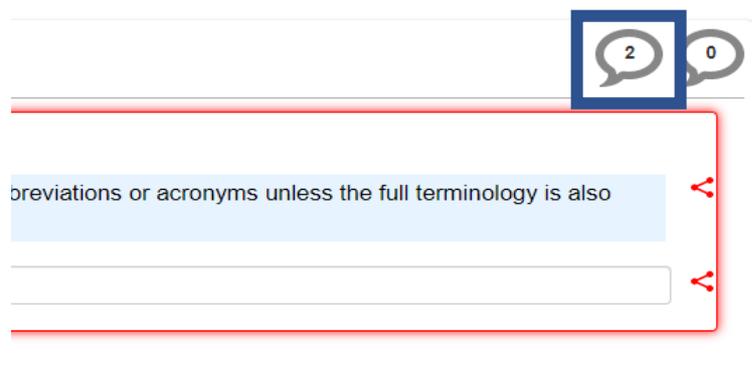
#### 1.1.1 Project Title \*

The title should reflect the research project or activity and not include abbreviations or acronyms unless the full terminology is also included

Test Project 6

#### 1.1.2 Provide a brief plain language description of the proposed project or activity, including the overall aim \*

You can also view the comments by clicking the speech bubble above the question



Once you have addressed the reviewer comments, resubmit the form.

**If you do not respond to the governance review within 60 days, the RGE will provide a ten (10) day reminder before withdrawing the request for amendment RM.**

### Administrative Changes

Remember at the start of this document we said some requests for amendment may be expedited? If your changes are purely administrative in nature and do not impact the ethical parameters of the project, these may be eligible for approval by the RGE Coordinator and your application may be approved at this point! The RGE Coordinator will let you know by providing you with a formal approval letter.

If changes are more involved, once any necessary revisions have been made or additional information provided and the RGE Coordinator is satisfied with the request for amendment RM, it will be forwarded for ethical review.

### Ethical Review

Once your request for amendment RM has been validated through the Governance Review process it will be forwarded to the relevant HREC or CHEAN. You will be able to track your request for amendment RM in REP to see when it has gone for ethical review – whether it has been sent to reviewers for an out of session review or if it has been scheduled for an in session meeting. If you do have questions, you can always reach out to [humanethics@rmit.edu.au](mailto:humanethics@rmit.edu.au).

The ethical review actions can be one of the following:

- approve the request for amendment RM as submitted
- approved pending modifications
- modifications and resubmission requested
- not approved; resubmission not requested

The HREC/CHEAN decision will be communicated to the PI within one week of the completed review.

Once your amendment RM is approved, the proposed changes to the project can commence. The RGE Coordinator will amend the record in REP to reflect changes to research personnel or the new end date of the application.