

## Guide: Human Research Ethics Request for Amendment (REP Projects)

After receiving the written approval from the RMIT HREC or an RMIT CHEAN for 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, Integrity and Governance. 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 <https://researchethics.rmit.edu.au> or via the **My Ethics** tab in the **Researcher Portal**. REP is part of the RMIT single sign on and you can log in using your RMIT e-number or student s-number and password.

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

Amendments that require approval include, but are not limited to:

- Extensions
- changes in Principal Investigator (PI)
- inclusion/exclusion criteria such as:
  - o participants
  - o sites of study
  - o recruitment strategy
  - o consent and authorisation process
  - o participant information and consent form
  - o questions on survey/interview/focus groups
  - o testing procedures
  - o confidentiality measures or other 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) and remember to include your original application number in your email!

### How long will the process take?

It is the Project Owner's responsibility to allow enough time for the ethical review process. 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.

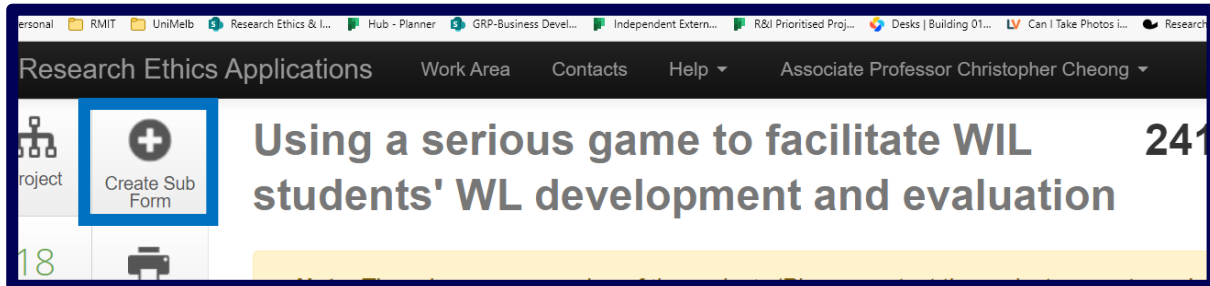
Factors that may have an impact on the timeframe for review include:

- the completeness and quality of the amendment request
- the nature of the amendment to be made
  - o administrative amendments can typically be reviewed and approved by the RGE Coordinators
  - o 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 supply requested information
- potential wait for external documents or letters of permission from related items.

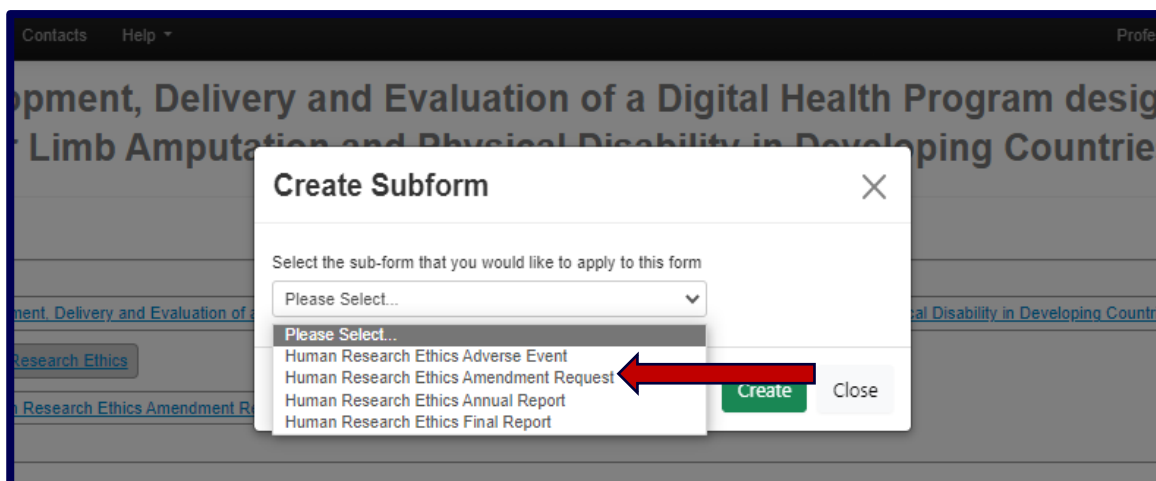
We recommend you start your request for amendment at least **six (6) weeks** before you need to make the change in your project. This will allow time for all steps in this process including the governance review, discussions and any necessary modifications, and then ethical review. This document will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

## Creating a New Request for Amendment

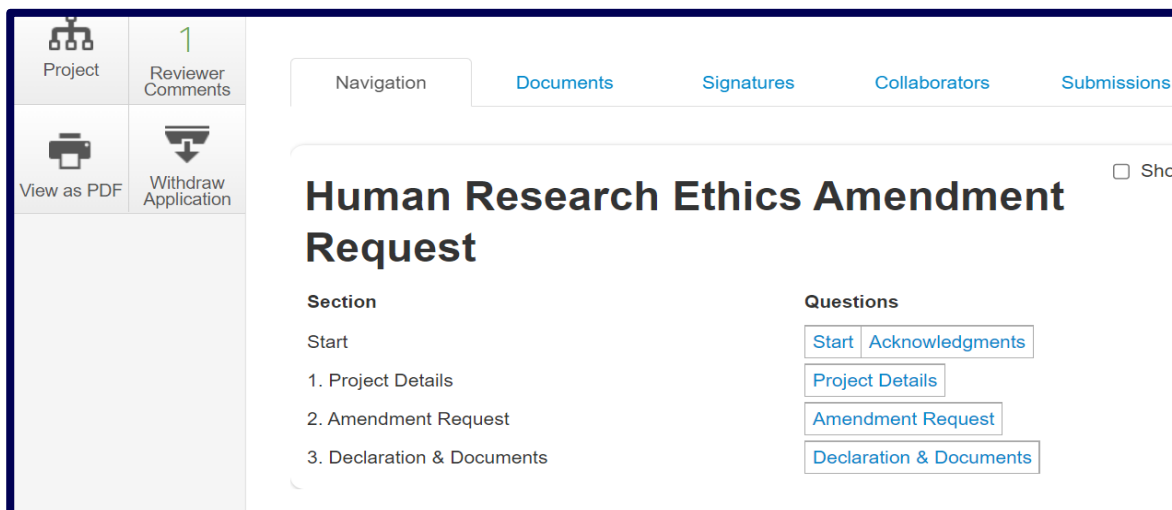
**Step 1:** From your work area, select the project you wish to amend and on the **Action Panel**, click **Create Sub-form**.



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



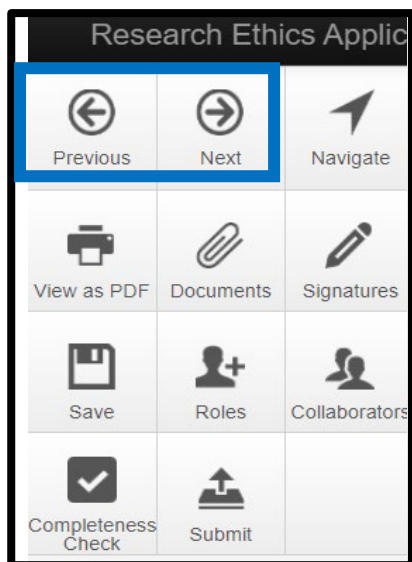
**Step 3:** You are now in the application form. To begin, click the **Start** section.



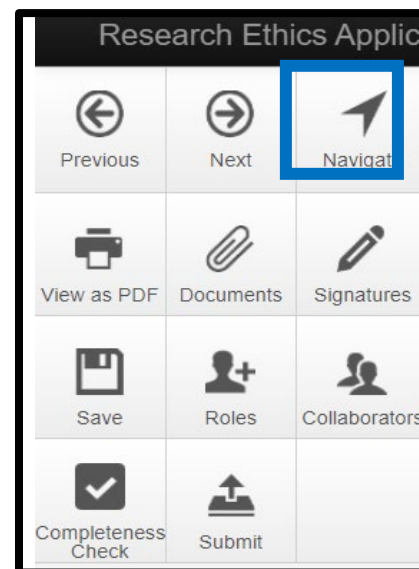
Directions for completing the request for amendment are imbedded within the form. This guide is designed to sit alongside REP as you familiarise yourself with the RMIT ethics process. More detailed REP instructions are also available in the help section of REP along with other guidance notes, guides and templates.

RGE Coordinators are available to help researchers in answering questions on completing the request for amendment 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:



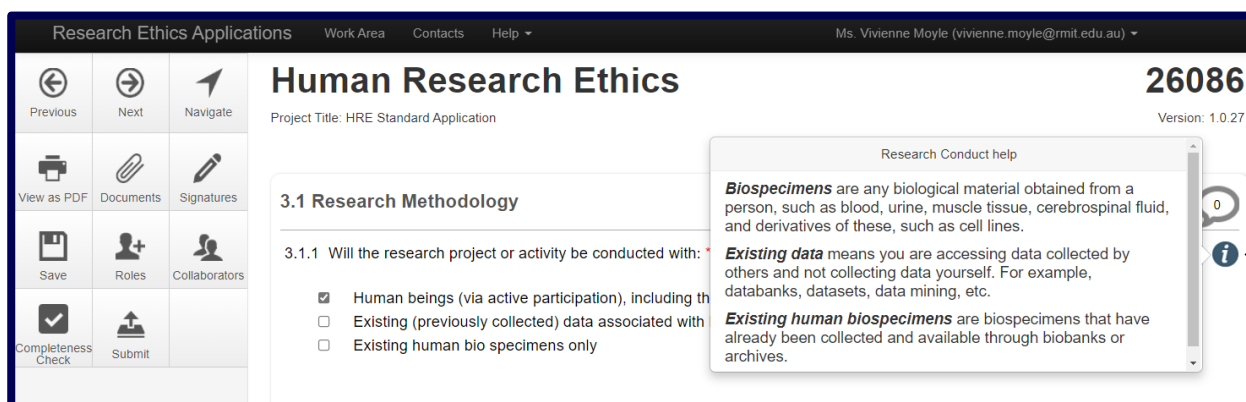
Within the **Action Panel** on the left-hand side of the screen, use the **Previous** and **Next** buttons to move between sections within the form or use **Navigate** to return to the form overview



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.

As you move through the request for amendment form, you will notice some text shaded in blue. These 'blue boxes' are tips to help you understand that specific information relating to ethics and research is needed for that question. You can also find more guidance by clicking on the information icon (i) within each question.



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*. Nothing should be blank.

# Completing the Request for Amendment

## Section 1: Project Details:

### 1.1 Project Title, Principal Investigator, Duration of Project.

The good news is – this section will auto populate from your original project application! Only the Principal Investigator will be listed here as they have primary responsibility for the project.

## Section 2: Amendment Request

### 2.1 This request is to amend:

Select all that apply. If you select 'Other' you will be asked to specify what it, you want to amend. This includes things like a change in Project Title.

**2.1 Request Details**

2.1.1 This request is to amend \*:

- ☐ the Research Team
- ☐ the Research Methodology
- ☐ the Recruitment Protocol
- ☐ the Informed Consent Process
- ☐ the process for collecting Human Research Data
- ☐ the process for collecting Human Bio-specimens Data
- ☐ the Research Data Management Protocol
- ☐ the Ethics Approval Period
- ☒ Other

2.1.1.1 Please specify \*

### 2.1.2 Will this amendment involve changes to:

Again, check all that apply. Selecting 'Other' will prompt you to specify the changes.

**2.1.2 Will this amendment involve changes to \***

2.1.2.1 the Research Instruments? \* ☐ Yes ☒ No

2.1.2.2 Data Collection Instruments? \* ☐ Yes ☒ No

2.1.2.3 Biospecimen Collection Instruments? \* ☐ Yes ☒ No

2.1.2.4 Participant Information and Consent Form/s? \* ☒ Yes ☐ No

2.2.1.5 Other \* ☐ Yes ☒ No

2.2.2 Please provide a brief (150 words or less) overview of the amendment \*

### 2.2.2 Please supply a brief (150 words or less) overview of the amendment

Use short, clear sentences. Use bullets or timetables for multiple visits or procedures. Select an easy-to-read font size.

- Amendment 1: Change to the research team
- Amendment 2: Addition of an assent document for children
- Amendment 3: Change of research methodology

By listing each item separately, it is very clear to the reviewer that there are three changes and in what area of the original application they 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.

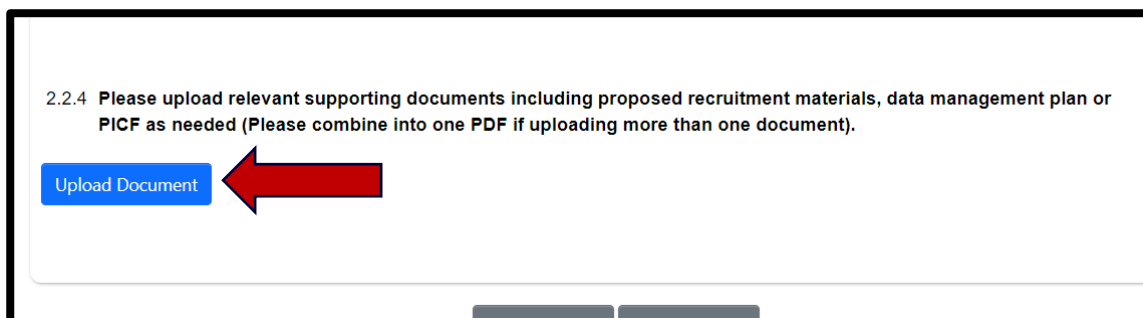
### 2.2.3 Please outline the rationale for the amendment, referencing any relevant ethics guidelines or considerations

Again, using bullets relates the rationale back to each amendment and will make the review go smoothly and show how you have considered the ethical principles in relation to any changes.

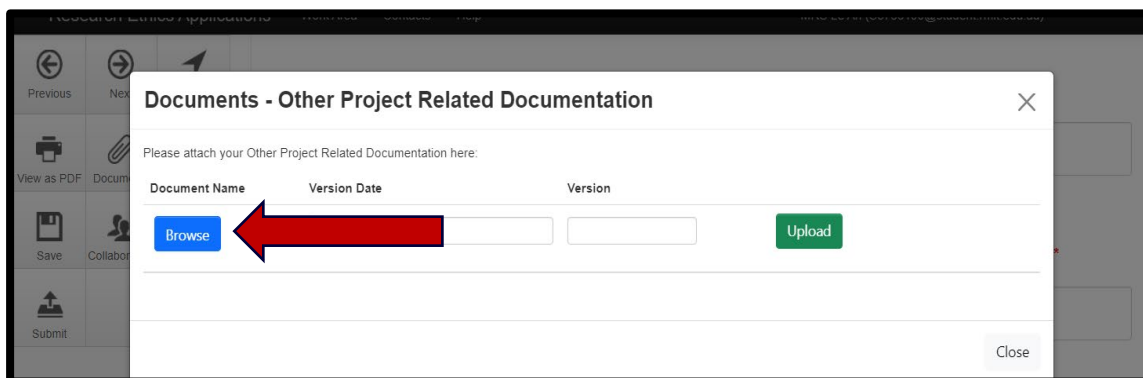
### 2.2.4 Please upload relevant supporting documents including proposed recruitment materials, data management plan or PICF as needed (Please combine into one (1) PDF document).

REP allows for the upload of one document to the Request, if you have changes to multiple supporting documents, please ensure you combine them into one (1) PDF document before uploading. This will ensure that the reviewers have all the amendments in front of them.

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

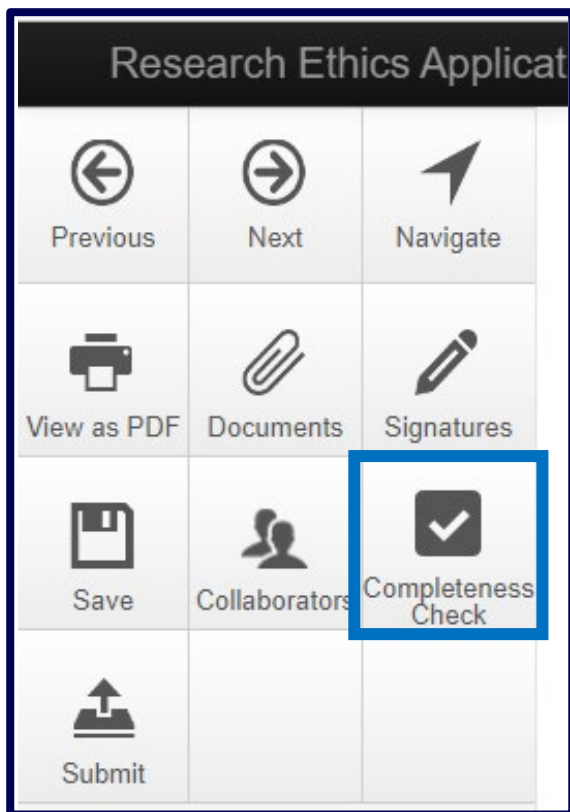


Click the **Browse** button to find the relevant file. Assign a version date and number for each document you upload and use consistent file naming conventions. And then click **Upload**.



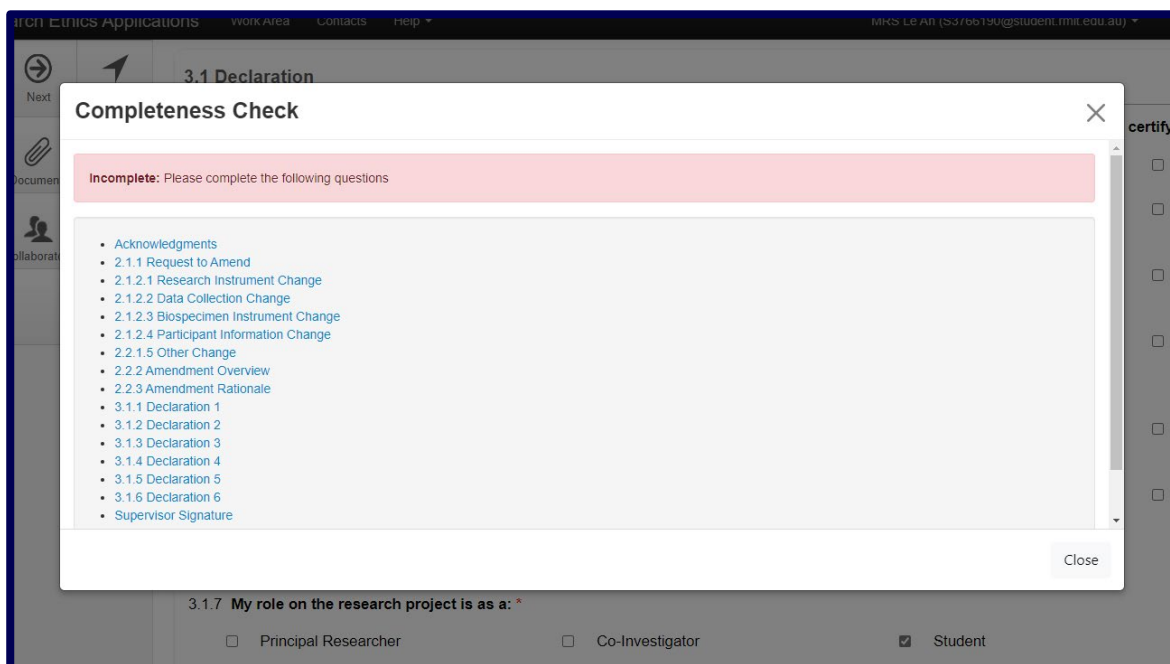
## Section 3: Declaration & Documents

### Validating the Form



When you have answered all the required questions and uploaded any required information, you need to click the **Completeness Check** button in the **Action Panel**.

The system will check that all mandatory questions have been addressed. A list of mandatory question 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 Amendment Request

### Obtaining Form Signatures

If you are submitting the form as either a co-investigator or a student on a project, you will have to obtain the signature of the Principal Investigator.

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

The screenshot shows the 'Research Ethics Applications' web interface. The top navigation bar includes 'Work Area', 'Contacts', and 'Help'. The user is logged in as 'MRS Le An (S3766190@student.rmit.edu.au)'. The left sidebar contains icons for 'Previous', 'Next', 'Navigate', 'View as PDF', 'Documents', 'Signatures', 'Save', 'Collaborators', 'Completeness Check', and 'Submit'. The main content area is titled '3.1 Declaration' and contains a list of statements for declaration, each with a checkbox. A red arrow points to the 'Request Signature' button at the bottom left of the form.

**3.1 Declaration**

In submitting this amendment request, all named researchers (Principal Investigator, Co-Investigators and Student Investigators), certify that \* :

3.1.1 All information in this form and supporting documentation is accurate and as complete as possible \* ☐

3.1.2 We are familiar with and have addressed in this form the requirements of the National Statement and any other relevant guidelines. \* ☐

3.1.3 We are familiar with and have considered and addressed in this form any relevant legislation, regulations, research guidelines and RMIT policies. \* ☐

3.1.4 We will ensure that the qualifications and/or experience of all researchers involved in the project are appropriate to their amended role and/or to the amended procedures performed (as applicable) and provide appropriate supervision to any student researchers (as applicable). \* ☐

3.1.5 We will continue to disclose and appropriately manage all relevant conflicts of interests of the project team in keeping the National Statement and RMIT Policy. \* ☐

3.1.6 We understand that the information contained in this form will be managed in accordance with relevant RMIT Policy and legislation. \* ☐

3.1.7 My role on the research project is as a: \*

☐ Principal Researcher ☐ Co-Investigator ☒ Student

Prior to submission, this application will require a signature from your Primary Senior Supervisor. \*

[Request Signature](#)

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

### Form Submission

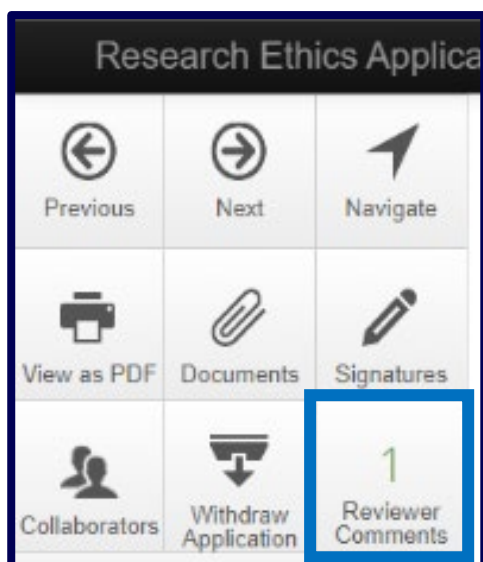
Once all mandatory questions have been completed, the request for amendment can be submitted for review by clicking the Submit button in the **Action Panel**. Then click Submit again in the next pop-up screen to confirm.

## What Happens Next?

### First Review: Governance

Within three business days of submitting a completed request for amendment 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 or changes are needed. The form is unlocked for you to make add information or make changes and the status of the form is updated to 'Revision Required.'

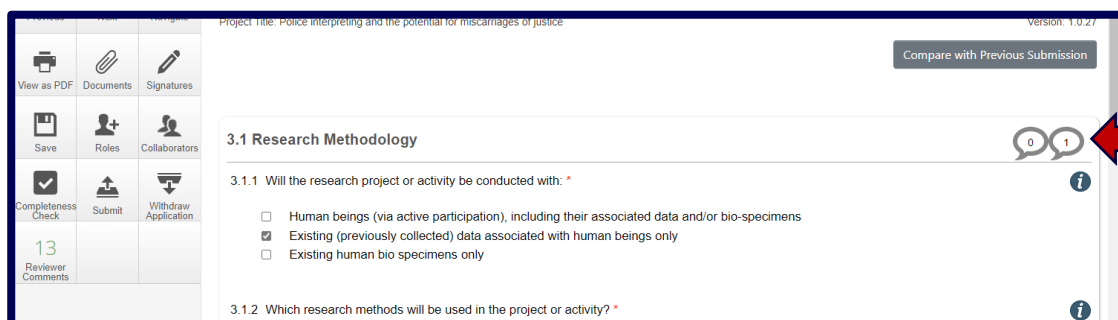


To view the comments made during governance review, click the **Review Comments** button on the **Action Panel**.

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.

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



Any required changes to supporting documents (PICF, recruitment material etc.) should be made using track changes and uploaded to the relevant sections of the form, with a new date and version control number. **Do not delete previous versions!**

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 supply a ten (10) day reminder before withdrawing the request for amendment.**

### Administrative Changes

If your changes are purely administrative in nature and do not affect 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 and next step instructions (see the final section of this guidance).

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

### Second Review: Ethical Review

Once your request for amendment has been validated through the Governance Review process it will be sent to the relevant HREC or CHEAN. You will be able to track your request for amendment



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 outcomes can be one of the following:

- approve the request for amendment 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.

## Finalising the Amendment

Once you have received notice that your amendment has been accepted, you will need to make relevant changes to the original full-length submission.

The RGE Coordinator will unlock the original submission so that you can complete this final piece.

**You must only make the changes that are in the amendment request.**

**Step 1:** Make the changes according to your Request for Amendment. For example, if you asked to change your recruitment strategy, then you will need to make changes to Section 5 of the form. Please also upload any revised supporting documents such as the PICF as per the amendment request to Section 9 of the form. Make sure you label them using version control and date. **Do not delete your prior versions.**

**Step 2:** Once you have updated the relevant sections of the form, please follow the usual process for submission. This may include requesting the signature of the Principal Investigator.

**Step 3:** The RGE Coordinator will check the changes made and finalise the approval of the amendment request or request further clarification/details as necessary. **Do not implement the changes until you have received your approval notice.**