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## Purpose of this guide

Human research projects conducted at the University of Newcastle – or by staff and students at the university – must have ethical approval before the research can begin.

Researchers can apply for approval of new research projects in the Human Ethics section of RIMS.

The information you enter in the 'Initial / New Project' application will help determine the level of review required for that application

You will also need to provide supporting documents, such as participant information statements and consent forms, etc.

This guide steps you through the process of creating an 'Initial / New Project' ethics application.

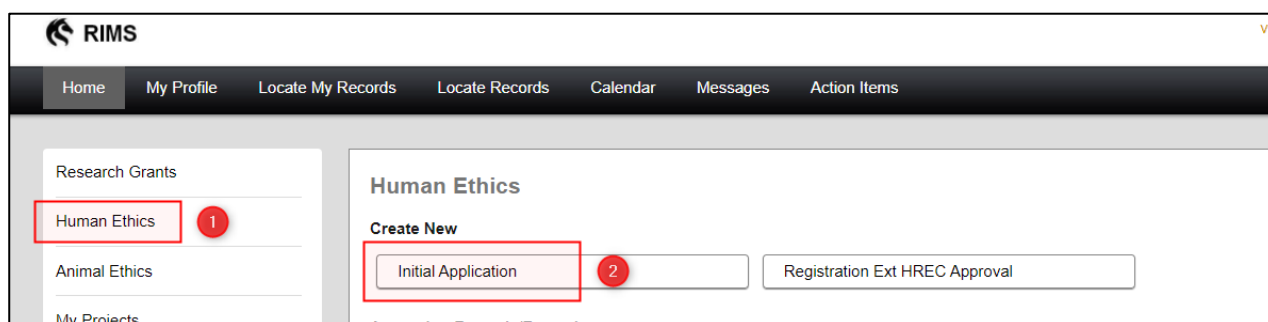
## Creating an Initial / New Project application

Applications are created on an eForm is reviewed by the University's Human Research Ethics Committee or your College review panel.\*

1. Once you have logged in to RIMS, navigate to your Human Ethics page.
2. Select the submission type you wish to create – in this case 'Create New / Initial Application'.

This will create an 'Initial / New Project' application eForm.

Figure 1



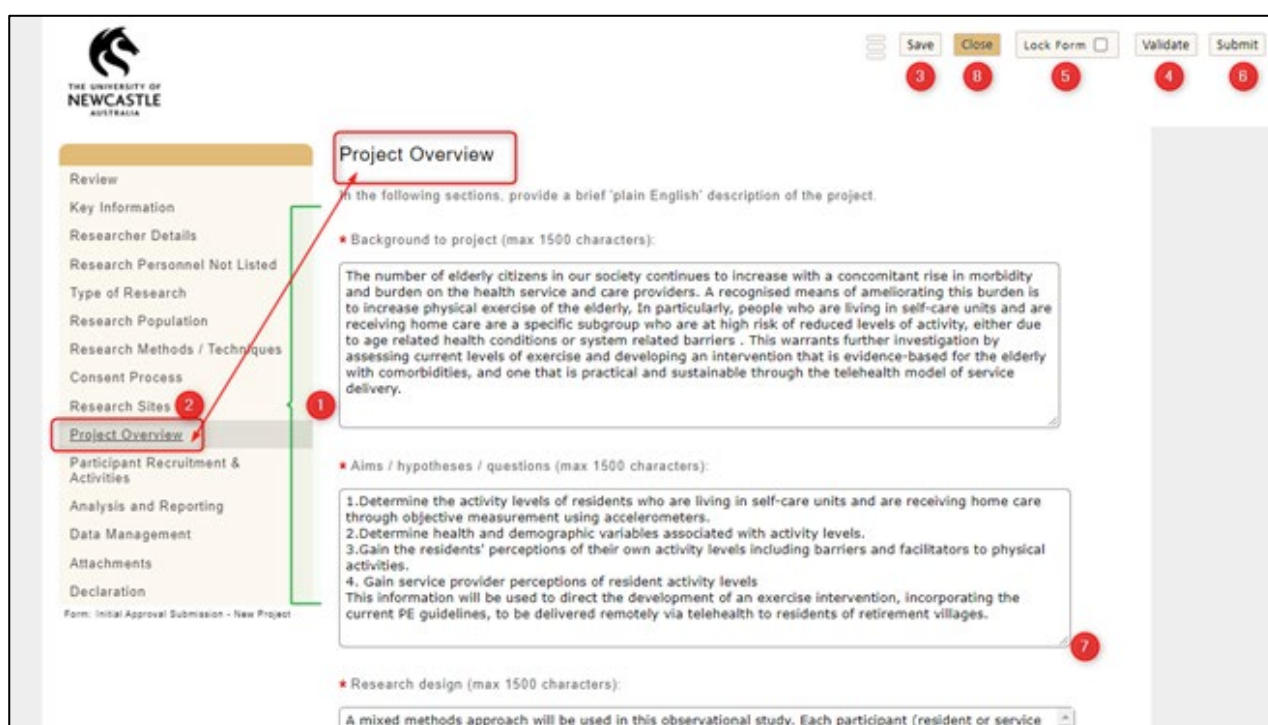
\* NOTE: From March 2022, the University will undertake a pilot project that will see College-based panels review and make determinations on 'negligible' and 'low-risk' ethics applications. The pilot involves two of our three Colleges – the College of Health, Medicine and Wellbeing and the College of Human and Social Futures. All Initial / New Project applications deemed to be 'more than low risk' will continue to be reviewed by the University's full Human Research Ethics Committee, including 'more than low risk' applications from the two Colleges involved in the pilot. Refer to the Human Ethics section of the [ReSearchHub](#) for more details about the pilot.

## Preparing your Initial / New Project application eForm

### Navigating the new eForm display

After creating the application (see Figure 1), you can start entering information into the Initial /New Project application eForm. The eForm will open on the **Key Information** tab, but you can move freely between different fields as you add content.

Figure 2



Some of the most common sections you'll use are summarised below. More detail for each is included within this guide.

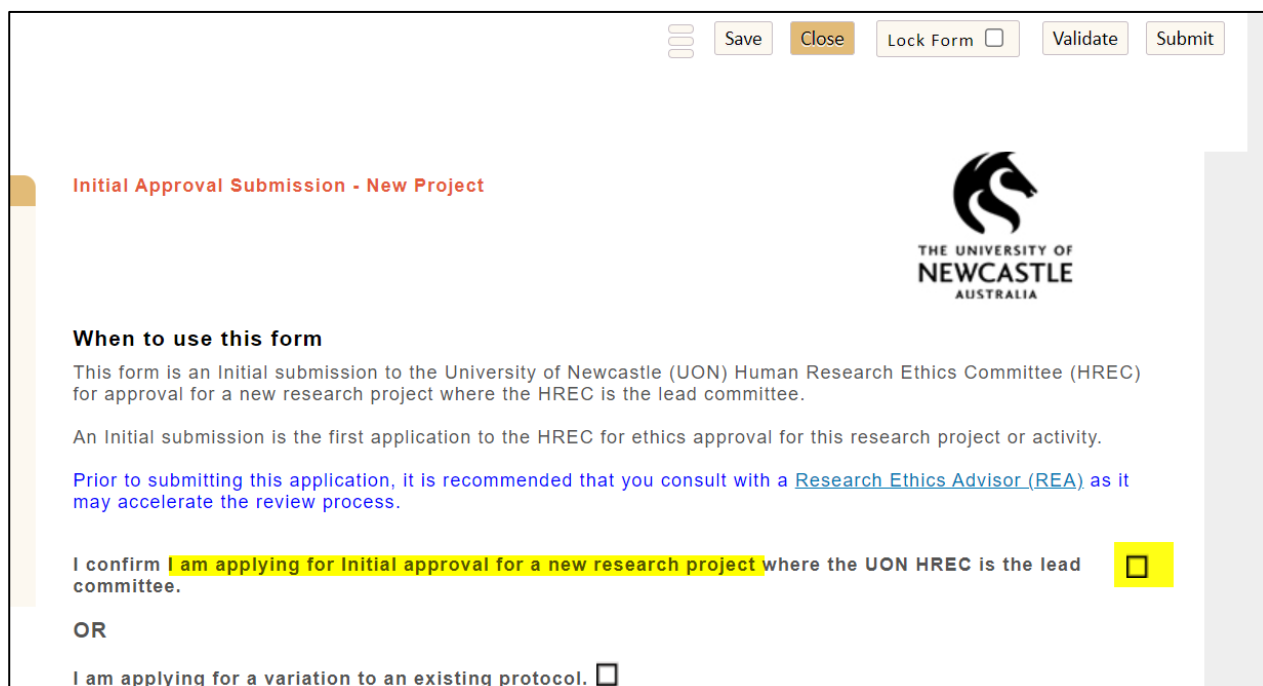
1. **eForm tabs:** The eForm features a series of tabs (or sections) which correspond to different aspects of the application. You can navigate through the form by selecting respective tabs located along the left of the screen. You can complete tabs / sections in any order, but mandatory fields (which are denoted by a red \* ) need to be completed before you can generate a PDF version for Head of School or Peer Review declarations.
2. **Tab display:** The eForm screen will display the required content for each tab / section as it's selected. For example, if you've selected the Project Overview tab as highlighted in Figure 2, you will see the fields that need to be completed, directions for character count, etc.

- 3. Save:** Save content entered to the eForm frequently to prevent any unforeseen data loss.
- 4. Validate:** This function will tell you whether you have completed all mandatory questions, and if not, which ones remain open.
- 5. Lock:** You must lock the eForm to generate a PDF version to share with peer reviewers and your Head of School, and to submit the application. The eForm can only be locked once all mandatory fields have been completed.
- 6. Submit:** Once you have added all the relevant and required content to the eForm, you will need to select the **Submit** option, which will be at the top right of your screen. Once submitted, the University's Human Research Ethics team will determine the review pathway based on the application type and whether your College is part of the pilot project (see page 2).
- 7. Field expand:** Drag the bottom right-hand edge of a question field down to expand it.

## Selecting your application type

The new eForm is now used for both Initial / New Project applications as well as Variation Applications (See the *Preparing a Variation Application* User Guide for advice on making a variation request.) Therefore, you will need to select the type of application you want to create within the **Key Information** tab, as shown in Figure 3.

Figure 3



Initial Approval Submission - New Project

THE UNIVERSITY OF  
NEWCASTLE  
AUSTRALIA

**When to use this form**

This form is an Initial submission to the University of Newcastle (UON) Human Research Ethics Committee (HREC) for approval for a new research project where the HREC is the lead committee.

An Initial submission is the first application to the HREC for ethics approval for this research project or activity.

Prior to submitting this application, it is recommended that you consult with a [Research Ethics Advisor \(REA\)](#) as it may accelerate the review process.

I confirm **I am applying for Initial approval for a new research project** where the UON HREC is the lead committee.

OR

I am applying for a variation to an existing protocol.

# Human Research Ethics

## RIMS User Guide

### Preparing and submitting an 'Initial / New Project' application



## Nominating your risk level

The *National Statement on Ethical Conduct in Human Research* defines the risk that a specific research initiative could potentially expose participants to in three ways: **Negligible, Low** and **More than Low risk**.

**Figure 4**

**Negligible Risk Research** – describes research in which there is no foreseeable risk of harm or discomfort, and any foreseeable risk is no more than inconvenience. E.g. minor survey or interview on a benign topic, giving up time.

**Low Risk Research** – describes research in which the only foreseeable risk is one of discomfort. E.g. minor side effects, discomfort associated with blood pressure measurement, emotional discomfort induced by an interview or survey, management of relationships involving a power imbalance, embarrassment, management of incidental findings or observations, risks to confidentiality and privacy.

Applications which fall into the above categories of risk are eligible for expedited review.

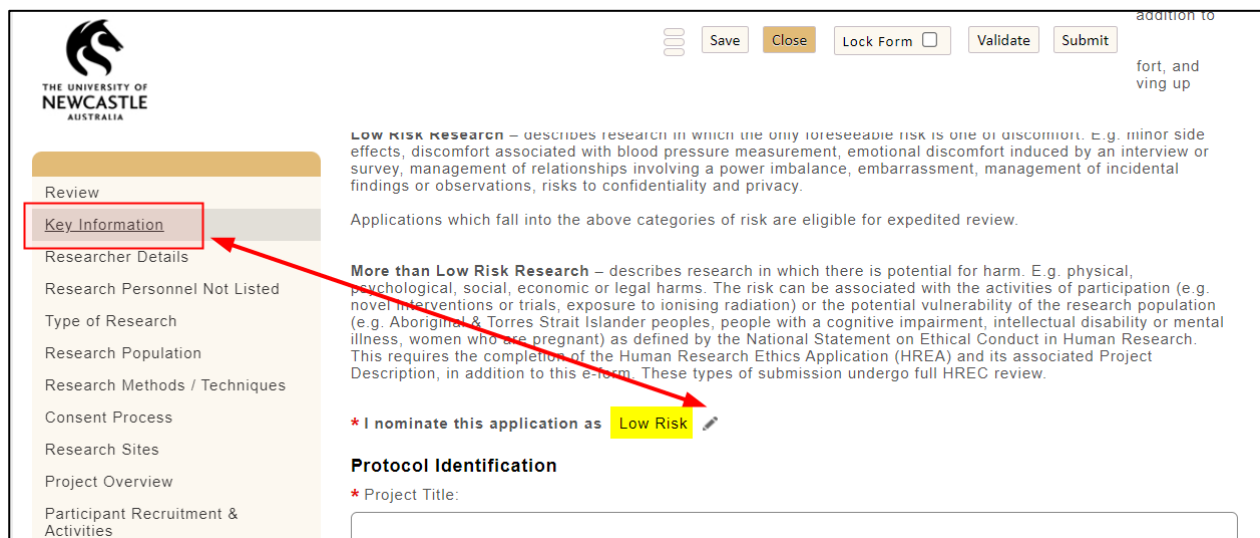
**More than Low Risk Research** – describes research in which there is potential for harm. E.g. physical, psychological, social, economic or legal harms. The risk can be associated with the activities of participation (e.g. novel interventions or trials, exposure to ionising radiation) or the potential vulnerability of the research population (e.g. Aboriginal & Torres Strait Islander peoples, people with a cognitive impairment, intellectual disability or mental illness, women who are pregnant) as defined by the National Statement on Ethical Conduct in Human Research. This requires the completion of the Human Research Ethics Application (HREA) and its associated Project Description, in addition to this e-form. These types of submission undergo full HREC review.

The level of risk informs the [review pathway](#) for your ethics application. The eForm gives you the opportunity to request a level of risk appropriate to your project and the research activities you propose.

If you are unsure of what level to nominate, [contact the Research Ethics Advisor appointed to your School or Division](#) for advice.

You can nominate the level of risk associated with your research in the **Key Information** tab as shown in Figure 5.

Figure 5



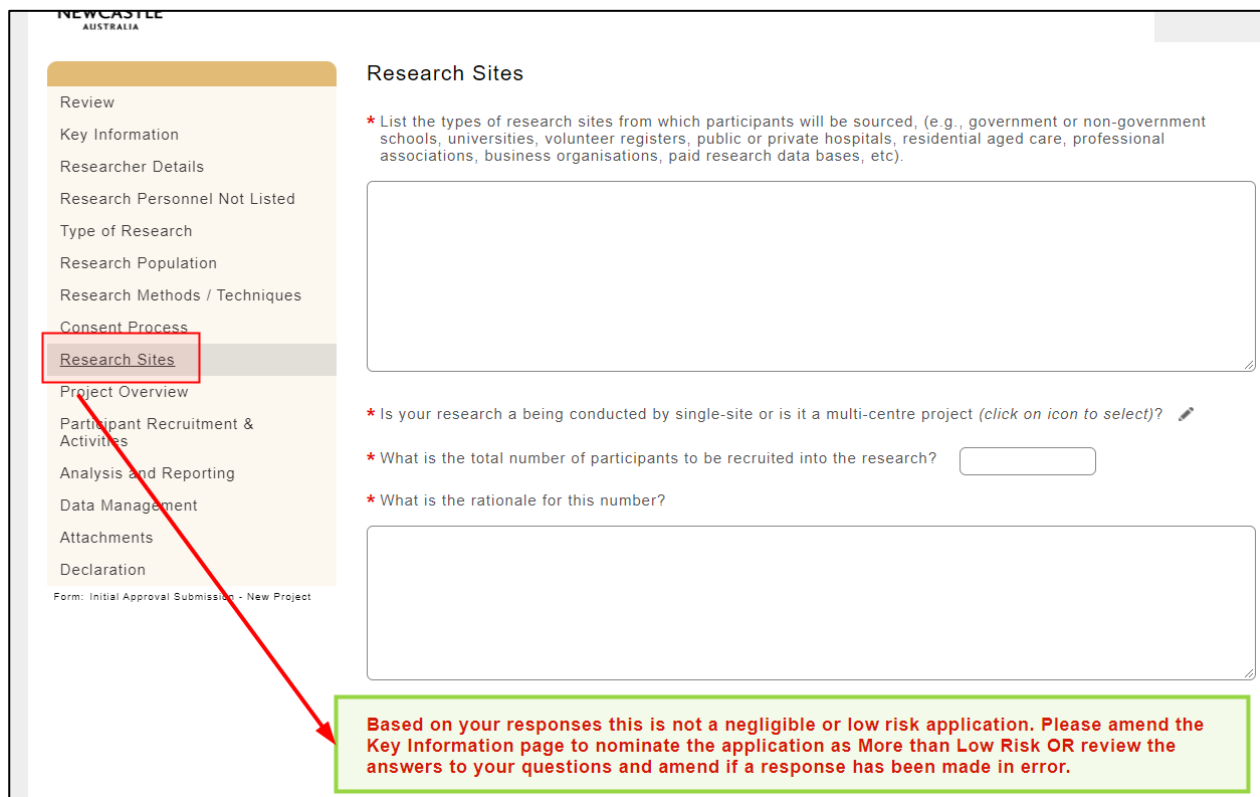
The screenshot shows the RIMS application form interface. On the left is a navigation menu with the University of Newcastle logo and a list of sections: Review, Key Information (highlighted with a red box), Researcher Details, Research Personnel Not Listed, Type of Research, Research Population, Research Methods / Techniques, Consent Process, Research Sites, Project Overview, and Participant Recruitment & Activities. The main content area is titled 'Low Risk Research' and contains text describing low risk research and its eligibility for expedited review. Below this is a section for 'More than Low Risk Research' and a nomination dropdown menu currently set to 'Low Risk'. A red arrow points from the 'Key Information' menu item to the 'Low Risk' button. At the top right of the form are buttons for Save, Close, Lock Form, Validate, and Submit.

If you select a risk level that is not compatible with your proposed research, you will receive a notification within the **Research Sites** section as shown in Figure 6.

For example, if you nominate a Negligible or Low Risk pathway but indicate your recruitment will focus on a vulnerable population, you will need to adjust your risk nomination accordingly.

If you receive a notification but believe your research *is* Negligible or Low risk, review your answers to questions in earlier sections of the eForm to ensure they are accurate.

Figure 6




The screenshot shows the 'Research Sites' section of the RIMS application form. The left-hand navigation menu has 'Research Sites' highlighted with a red box. A red arrow points from this box to a green warning message at the bottom of the form. The main content area contains the following text and fields:

**Research Sites**

\* List the types of research sites from which participants will be sourced, (e.g., government or non-government schools, universities, volunteer registers, public or private hospitals, residential aged care, professional associations, business organisations, paid research data bases, etc).

[Empty text area]

\* Is your research a being conducted by single-site or is it a multi-centre project (click on icon to select)? 

\* What is the total number of participants to be recruited into the research?

\* What is the rationale for this number?

[Empty text area]

**Based on your responses this is not a negligible or low risk application. Please amend the Key Information page to nominate the application as More than Low Risk OR review the answers to your questions and amend if a response has been made in error.**

## Review pathway for More than Low Risk applications

If your application is deemed to be 'more than low risk' (either through your direct indication or as determined by the information you enter into RIMS), the eForm will automatically advise you to complete a [Human Research Ethics Application \(HREA\) form](#).

The HREA form has been developed by the National Health and Medical Research Council to provide consistency of information required on human research ethics applications that are more than low risk.

You will also need to prepare a [Project Description document](#), which is a partner document to the HREA form.

Your completed HREA form and Project Description document need to be uploaded as supporting documents when lodging your full application in [RIMS](#).

The [HREA Resources page](#) provides advice on how to create an account to access HREA resources, how to complete the application form, etc. For technical assistance on the HREA system, contact HREA Help on:

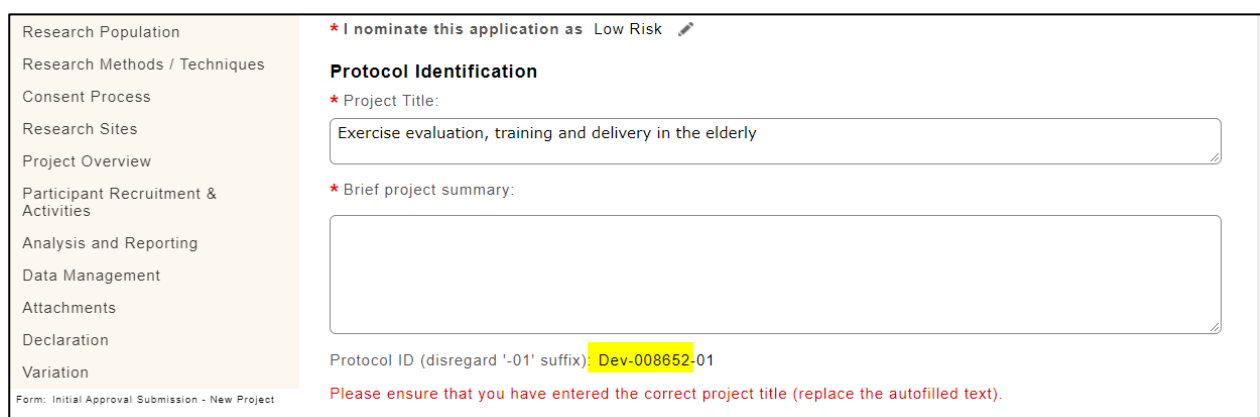



- (02) 6217-9451
- 1 800 500 983
- [help@hrea.gov.au](mailto:help@hrea.gov.au).

## Record ID: Finding your draft eForm

It's unlikely that you will complete the full eForm in one sitting and will therefore need to return to it over time. Please ensure you take note of the *Development number* within the **Key Information** section directly beneath the project summary field, as shown in Figure 7.

Figure 7



Research Population \* I nominate this application as Low Risk 

Research Methods / Techniques

Consent Process

Research Sites

Project Overview

Participant Recruitment & Activities

Analysis and Reporting

Data Management

Attachments

Declaration

Variation

Form: Initial Approval Submission - New Project

**Protocol Identification**

\* Project Title:

Exercise evaluation, training and delivery in the elderly

\* Brief project summary:

Protocol ID (disregard '-01' suffix): Dev-008652-01

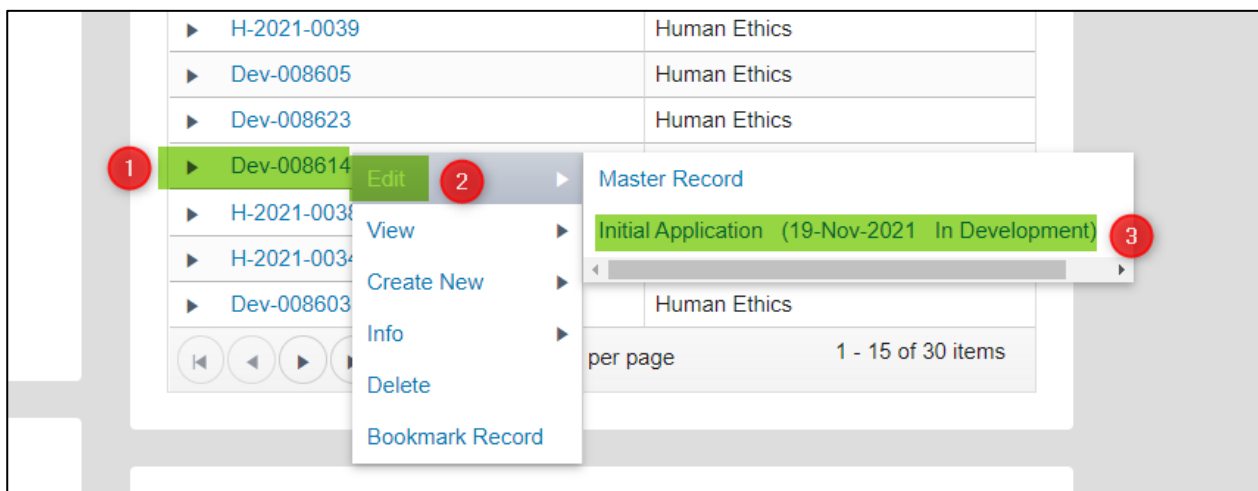
Please ensure that you have entered the correct project title (replace the autofilled text).

Use the first set of numbers (e.g., "Dev-008652") and ignore '01' suffix when you need use the Development number to return to your application.

If you are listed as the Chief Investigator (see **Researcher Details** tab), the Development number will appear when you select the **Locate My Records** option. For all other researchers listed on the eForm, please use the **Quick Find** search to return to your incomplete eForm.

Once you have identified this record select **Edit** and then **Initial application (date created In Development)** to resume your application as shown in Figure 8.

Figure 8

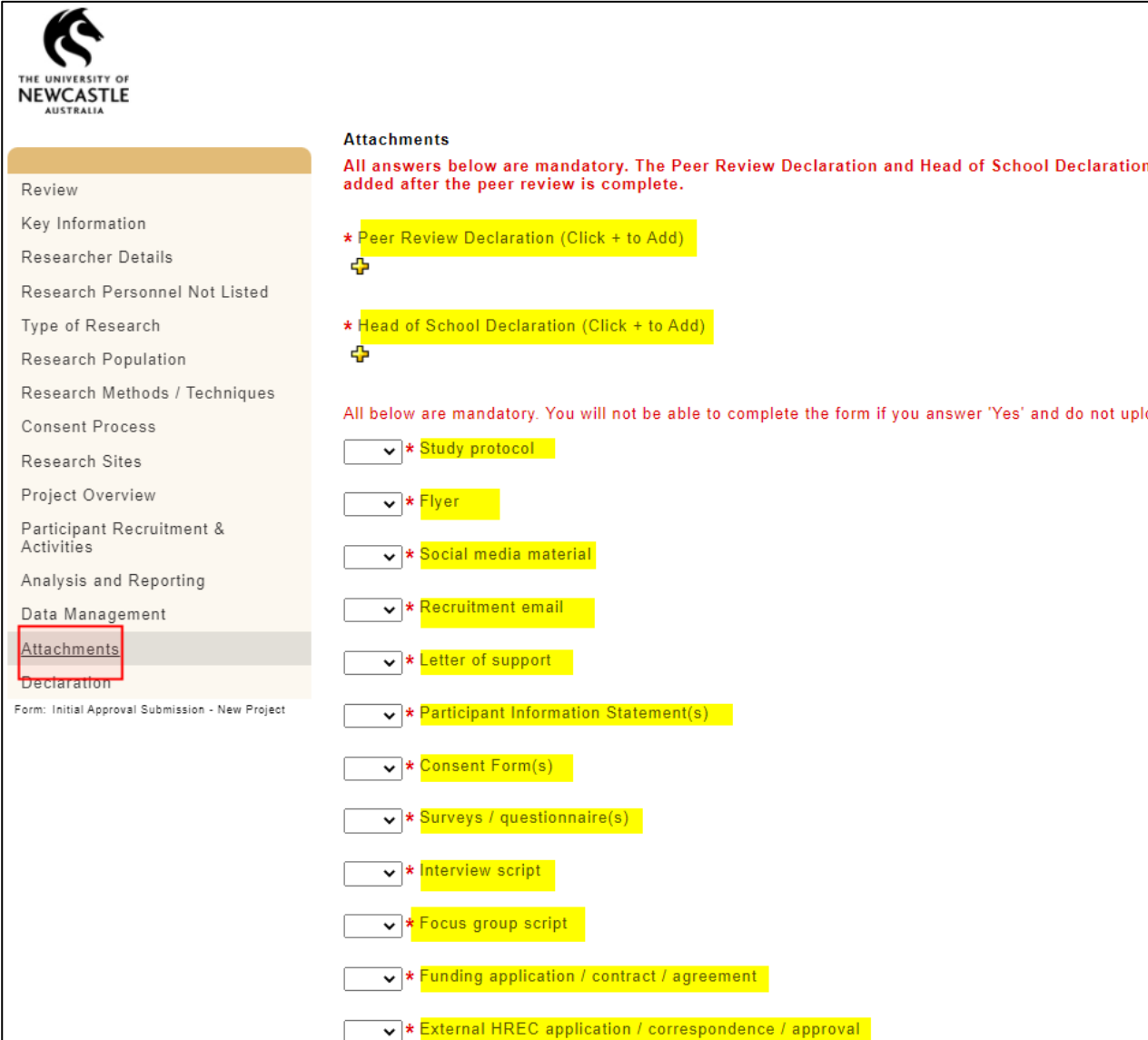


## Attaching supplementary documents

An Initial / New Application consists of the completed eForm and supporting documents, such as participant information statements and consent forms, letters of support, etc.

All attachments can be uploaded within the **Attachments** tab as shown in Figure 9.

Figure 9



**Attachments**

All answers below are mandatory. The Peer Review Declaration and Head of School Declaration added after the peer review is complete.

- \* Peer Review Declaration (Click + to Add)
- +
- \* Head of School Declaration (Click + to Add)
- +

All below are mandatory. You will not be able to complete the form if you answer 'Yes' and do not upload.

- ▼ \* Study protocol
- ▼ \* Flyer
- ▼ \* Social media material
- ▼ \* Recruitment email
- ▼ \* Letter of support
- ▼ \* Participant Information Statement(s)
- ▼ \* Consent Form(s)
- ▼ \* Surveys / questionnaire(s)
- ▼ \* Interview script
- ▼ \* Focus group script
- ▼ \* Funding application / contract / agreement
- ▼ \* External HREC application / correspondence / approval

The attachment categories cover the most common types of documents associated with an initial application. Attachments outside the pre-set category listings can be uploaded through the 'Miscellaneous' option.

Please note:

- Completed Head of School and Peer Review declarations are mandatory, and your application cannot progress to the review stage without them. However, if the proposed research has been peer reviewed as part of a competitive grant application, you do not need to source another

peer review.

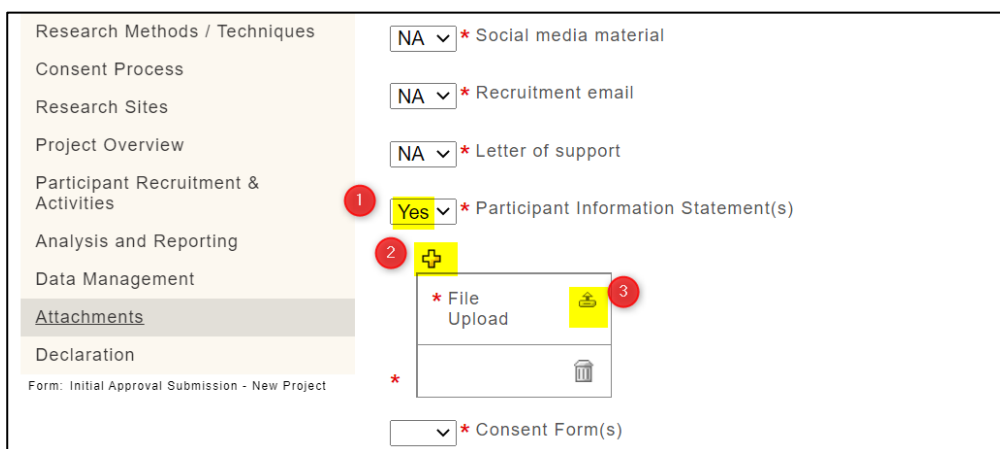
- Applications that are considered 'more than low risk' require a HREA and Project Description, as noted earlier in this guide. These two attachment categories will only display if 'more than low risk' has been nominated as the risk type for your research project.

## Uploading attachments

Follow these simple steps to upload attachments:

1. Within the **Attachments** section, select **Yes** or **NA** (not applicable) from the dropdown options for each attachment category. You will not need to make this selection for the Peer Review or Head of School declarations, as these are mandatory attachment categories.
2. For attachment categories where you have chosen **Yes**, you will need to select the add (+) sign.
3. From here, you can select '**File upload**'.

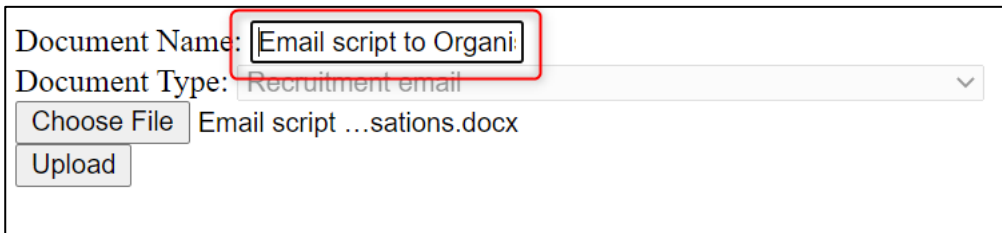
Figure 10



The screenshot shows the 'Attachments' section of the RIMS application. On the left is a sidebar with categories: Research Methods / Techniques, Consent Process, Research Sites, Project Overview, Participant Recruitment & Activities, Analysis and Reporting, Data Management, Attachments (highlighted), and Declaration. Below the sidebar is the text 'Form: Initial Approval Submission - New Project'. The main area contains several attachment categories, each with a dropdown menu and a red asterisk: 'Social media material' (NA), 'Recruitment email' (NA), 'Letter of support' (NA), 'Participant Information Statement(s)' (Yes), and 'Consent Form(s)' (dropdown). A red circle '1' points to the 'Yes' dropdown. A red circle '2' points to a yellow plus sign icon. A red circle '3' points to a yellow 'File Upload' button in a pop-up window that also contains a trash icon.

4. A window will appear that allows you to browse for and select the desired file. Once you have uploaded a document, ensure you enter the name of the file in the **Document Name** field as shown in Figure 11, as this will help make the review process more efficient.

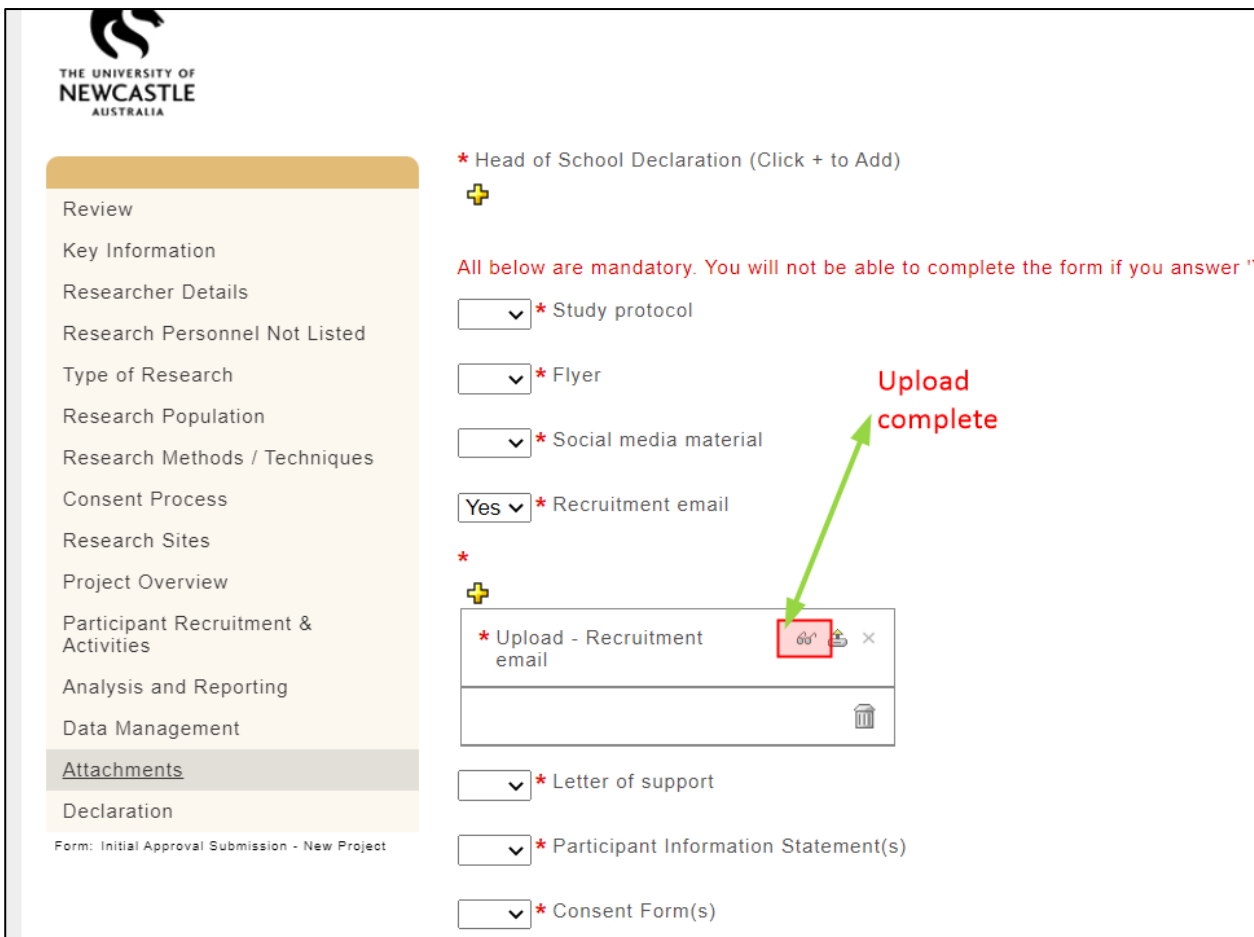
Figure 11



Document Name:   
Document Type:   
 Email script ...sations.docx

- Once you've completed step 4, select **Upload**. After the file has uploaded, an 'eyeglasses' icon will appear as shown in Figure 12. Click on this to view your file if necessary. Please ensure this icon appears for each upload, otherwise your file may not have uploaded correctly.

Figure 12



THE UNIVERSITY OF  
NEWCASTLE  
AUSTRALIA

Review  
Key Information  
Researcher Details  
Research Personnel Not Listed  
Type of Research  
Research Population  
Research Methods / Techniques  
Consent Process  
Research Sites  
Project Overview  
Participant Recruitment & Activities  
Analysis and Reporting  
Data Management  
**Attachments**  
Declaration

Form: Initial Approval Submission - New Project

\* Head of School Declaration (Click + to Add)  
+

All below are mandatory. You will not be able to complete the form if you answer 'No'

\* Study protocol  
 \* Flyer  
 \* Social media material  
 \* Recruitment email

\*  
+

\* Upload - Recruitment email

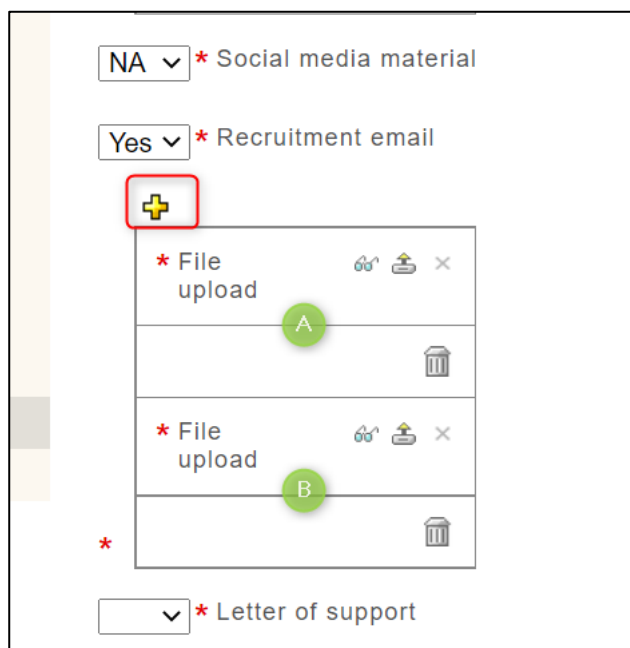
\* Letter of support  
 \* Participant Information Statement(s)  
 \* Consent Form(s)

Upload complete

If you need to upload multiple documents within the same attachment category, select the add (+) sign and complete steps 3 to 5 for each attachment. For example, you may need to upload

'Recruitment flyer A' and 'Recruitment flyer B'. See Figure 13 for a sample screen shot showing multiple file uploads.

Figure 13



The screenshot shows a portion of a web form. At the top, there are two dropdown menus: the first is set to 'NA' with a red asterisk and the text '\* Social media material'; the second is set to 'Yes' with a red asterisk and the text '\* Recruitment email'. Below these is a red-bordered box containing a yellow plus sign icon. Underneath this is a file upload interface with two rows. Each row is labeled '\* File upload' and has a green circle with a letter ('A' and 'B' respectively) in the center. To the right of each row are icons for refresh, upload, and delete. Below the second row is a red asterisk and a dropdown menu set to 'v' with the text '\* Letter of support'.

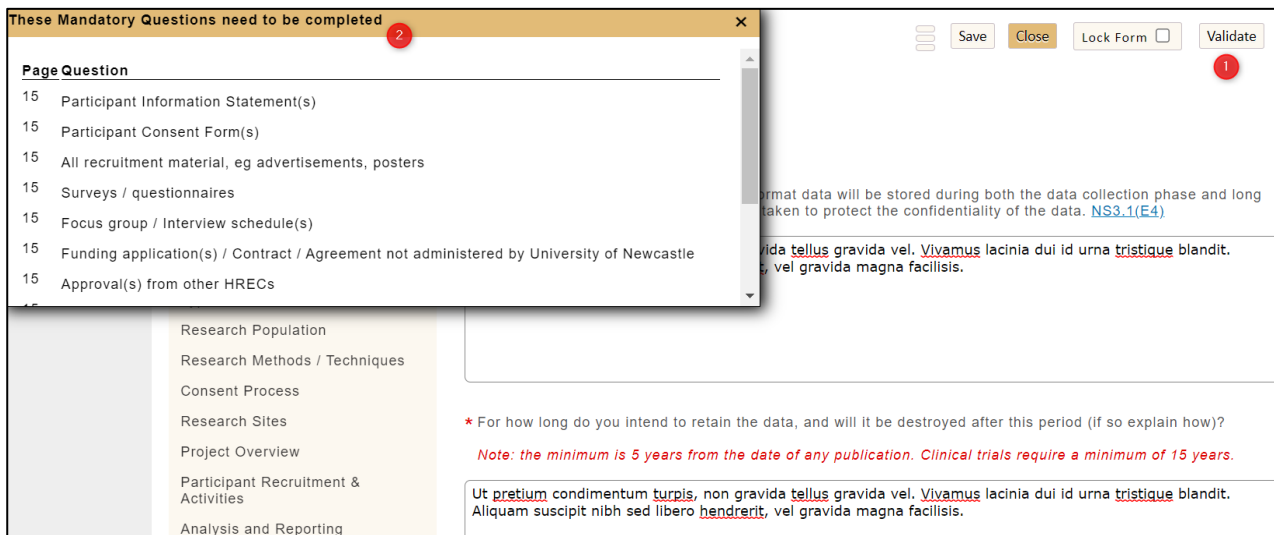
Please note that the file name of the attachment will not display once it has been uploaded. We acknowledge this is not ideal and have been assured by the software developer that this will be rectified during the next RIMS upgrade later in 2022.

## Validating your application information

Before finalising your Initial / New Project application, double check that you have completed all the mandatory fields in the eForm using the **Validate** function. To do this:

1. Select the **Validate** option from the menu in the top-right corner of the screen.
2. A list of mandatory questions that require action will appear, as shown in Figure 14 and 15.
3. Click on any of the questions to go to that section of the eForm and complete the required fields.

Figure 14



**These Mandatory Questions need to be completed** 2

**Page Question**

- 15 Participant Information Statement(s)
- 15 Participant Consent Form(s)
- 15 All recruitment material, eg advertisements, posters
- 15 Surveys / questionnaires
- 15 Focus group / Interview schedule(s)
- 15 Funding application(s) / Contract / Agreement not administered by University of Newcastle
- 15 Approval(s) from other HRECs

Research Population

Research Methods / Techniques

Consent Process

Research Sites

Project Overview

Participant Recruitment & Activities

Analysis and Reporting

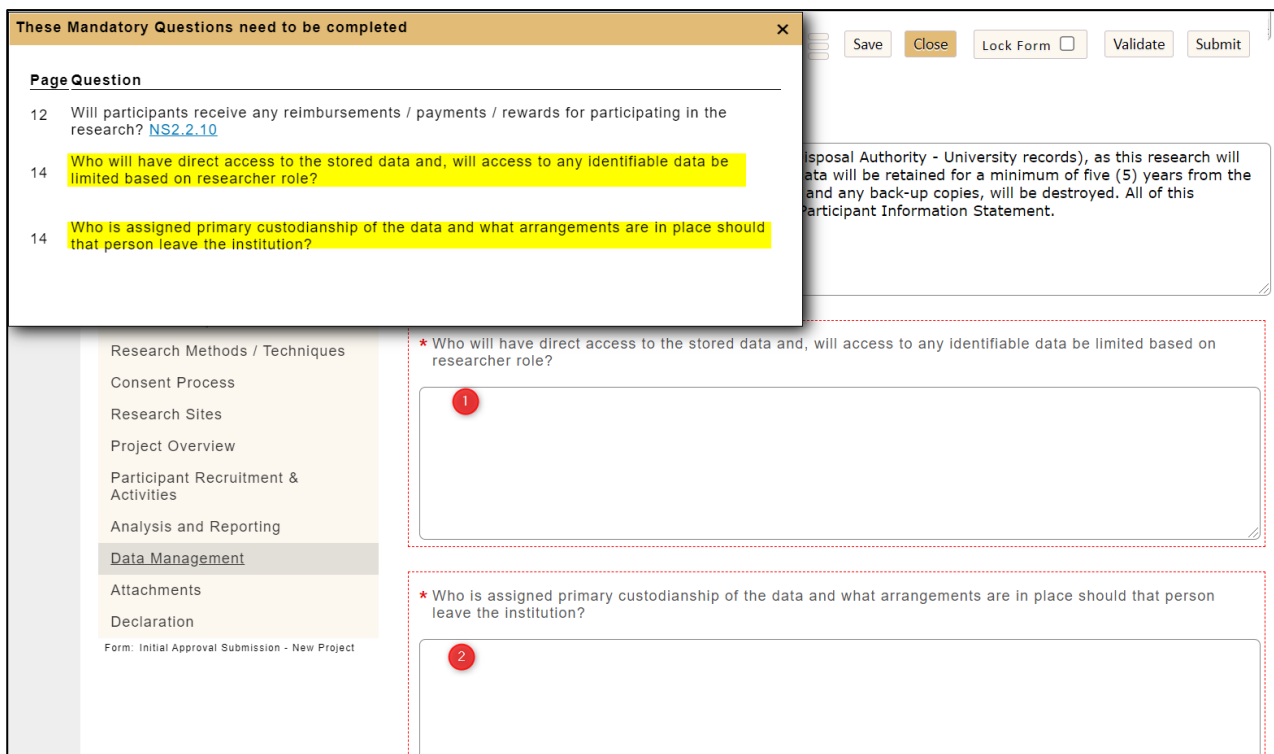
\* For how long do you intend to retain the data, and will it be destroyed after this period (if so explain how)?

*Note: the minimum is 5 years from the date of any publication. Clinical trials require a minimum of 15 years.*

Ut pretium condimentum turpis, non gravida tellus gravida vel. Vivamus lacinia dui id urna tristique blandit. Aliquam suscipit nibh sed libero hendrerit, vel gravida magna facilisis.

Save Close Lock Form  Validate 1

Figure 15



**These Mandatory Questions need to be completed** X

**Page Question**

- 12 Will participants receive any reimbursements / payments / rewards for participating in the research? [NS2.2.10](#)
- 14 Who will have direct access to the stored data and, will access to any identifiable data be limited based on researcher role?
- 14 Who is assigned primary custodianship of the data and what arrangements are in place should that person leave the institution?

Research Methods / Techniques

Consent Process

Research Sites

Project Overview

Participant Recruitment & Activities

Analysis and Reporting

**Data Management**

Attachments

Declaration

Form: Initial Approval Submission - New Project

\* Who will have direct access to the stored data and, will access to any identifiable data be limited based on researcher role?

1

\* Who is assigned primary custodianship of the data and what arrangements are in place should that person leave the institution?

2

Save Close Lock Form  Validate Submit

## Exporting the eForm for Peer Review and Head of School declarations

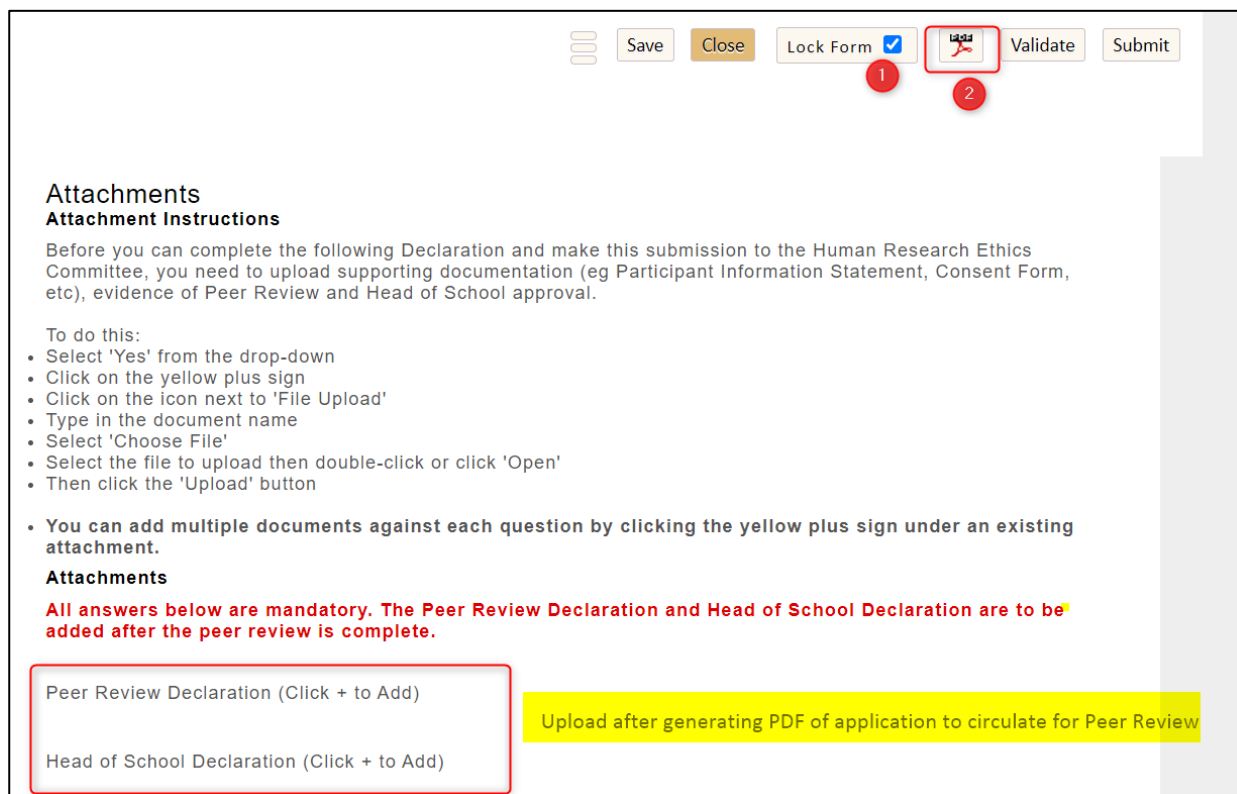
You will be required to export a copy of your ethics application as a PDF document so that it can be sent for peer review and Head of School sign off. To do this, follow the steps below and refer to Figure 16:

1. Ensure all mandatory questions in your application have been addressed, including those within the **Attachment** and **Declaration** sections.
2. Lock your eForm. If any mandatory questions remain unanswered, you will not be able to lock the form and will be prompted to complete the required sections.
3. Once you've locked the eForm, a PDF icon will appear in the top right of the screen. Click this icon to export your application to a PDF file.
4. Save the PDF file onto your OneDrive (or whatever file management system you use) and submit it for Peer Review and Head of School review, along with the appropriate templates which you can find on our internal [ReSearchHub](#):
  - [Peer Review Checklist](#)
  - [Peer Review Declaration Form](#)
  - [Head of School Declaration Form](#)

As a reminder, if the proposed research project has been peer reviewed as part of a competitive grant application, you do not need to source another peer review. Simply complete the relevant fields in the Peer Review Declaration Form.



Figure 16



Save Close Lock Form  Upload Validate Submit

### Attachments

**Attachment Instructions**

Before you can complete the following Declaration and make this submission to the Human Research Ethics Committee, you need to upload supporting documentation (eg Participant Information Statement, Consent Form, etc), evidence of Peer Review and Head of School approval.

To do this:

- Select 'Yes' from the drop-down
- Click on the yellow plus sign
- Click on the icon next to 'File Upload'
- Type in the document name
- Select 'Choose File'
- Select the file to upload then double-click or click 'Open'
- Then click the 'Upload' button

- You can add multiple documents against each question by clicking the yellow plus sign under an existing attachment.

**Attachments**

**All answers below are mandatory. The Peer Review Declaration and Head of School Declaration are to be added after the peer review is complete.**

Peer Review Declaration (Click + to Add)

Head of School Declaration (Click + to Add)

Upload after generating PDF of application to circulate for Peer Review

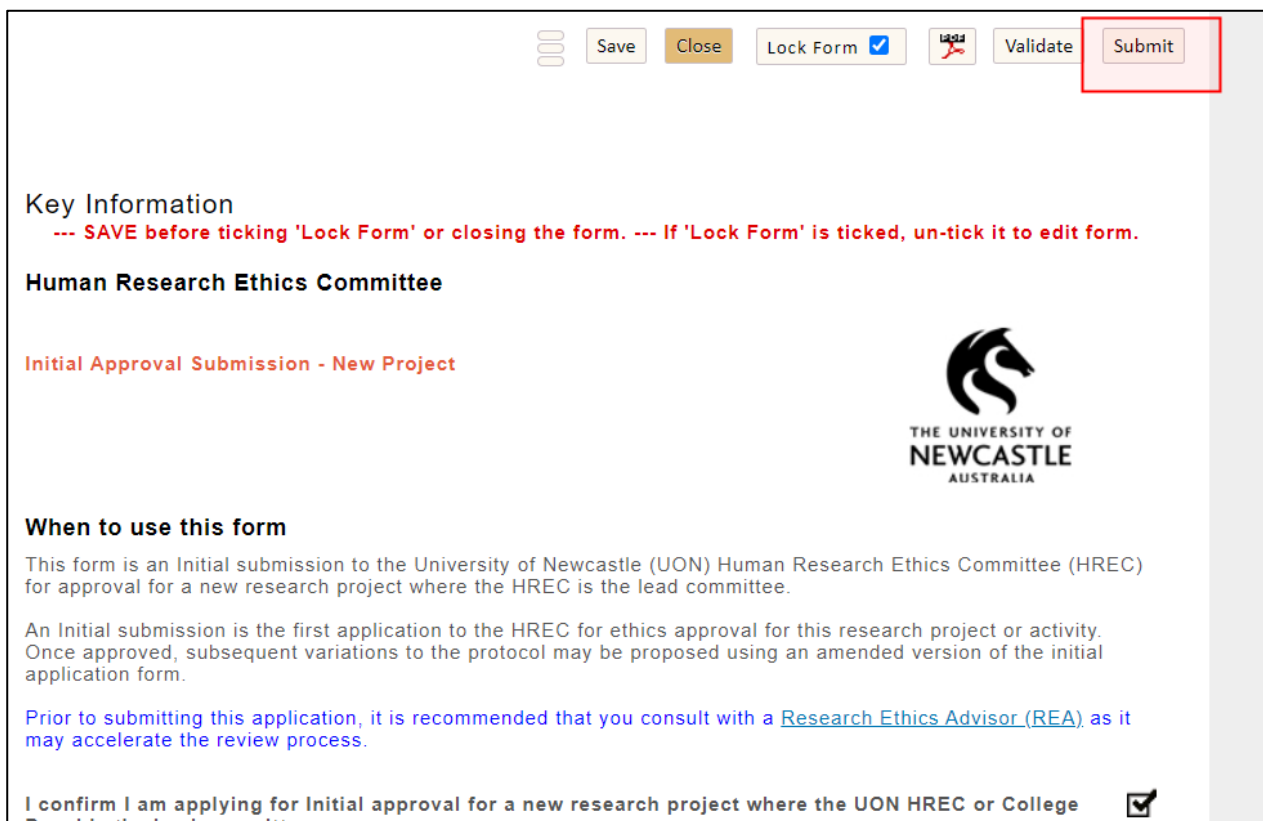
Once you have secured your Peer Review and Head of School declarations, you will need to log into RIMS, bring up your application (using your Development number) and then unlock the eForm.


You can then upload the declarations in the eForm in the **Attachments** section.

## Submitting your application for review

After you have uploaded your Peer Review and Head of School Declarations, **lock** your eForm again. It is now ready to submit. Submission can be completed from within the eForm, as shown in Figure 17.

Figure 17




Save Close Lock Form   Validate **Submit**

**Key Information**  
--- SAVE before ticking 'Lock Form' or closing the form. --- If 'Lock Form' is ticked, un-tick it to edit form.

**Human Research Ethics Committee**

Initial Approval Submission - New Project



**When to use this form**  
This form is an Initial submission to the University of Newcastle (UON) Human Research Ethics Committee (HREC) for approval for a new research project where the HREC is the lead committee.  
An Initial submission is the first application to the HREC for ethics approval for this research project or activity. Once approved, subsequent variations to the protocol may be proposed using an amended version of the initial application form.  
Prior to submitting this application, it is recommended that you consult with a [Research Ethics Advisor \(REA\)](#) as it may accelerate the review process.

I confirm I am applying for Initial approval for a new research project where the UON HREC or College

## For questions or support

If you have questions about the information in this guide or need additional support, please contact the Human Research Ethics team on [human-ethics@newcastle.edu.au](mailto:human-ethics@newcastle.edu.au).

**End of document**