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* 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 <u>ReSearchHub</u> for more details about the pilot.



Purpose of this guide

Most RIMS communication between researchers and the HREC / College panels will be slightly different following new system configurations in RIMS from March 2022. This is especially the case for 'Initial/New Project' applications and 'Variation' applications, as these types of applications are more likely to generate feedback.

You will continue to receive emails from the Human Ethics Team with attachments for applications that do not require you to respond to feedback (i.e., formal acceptances of some submissions and approvals).

For submissions that you need to respond to, you'll receive two kinds of notifications, which you can use to access your workflow assignment – and **Email Alert** and an **Action Item**.

Email Alert

If you need to respond to any feedback on a submission, *all* researchers listed on the protocol will receive an email notification to their university email account (unless they are externals). The actual content of the message will vary slightly, depending on what kind of outcome you need to respond to, however it will always be circulated in the format as shown below.

Subject Line:

Protocol Number: H-2021-0034 – Pre-Review Feedback | Initial Application

Body of email:

Your Application to the HREC has received **Pre-review Feedback**.

Please note: Only **Chief Investigators** should 'assign to self' and complete this assignment. If you are working on this assignment and accidently 'assign to self,' please contact Human Ethics, who will be able to unassign.

1. Select Assign to Self if ready to action. **Note that this will remove the assignment from the Action Items of other Investigators named on the protocol.**

2. To look at your Pre-review Feedback, open the **Add or Show comments** screen, which is accessible from the main menu at the top of this screen. Respond to your Pre-Review Feedback.

3. Make any changes to your application/attachments as required. **Note that you will need to unlock the eForm to make any changes to it.**

4. **Save** changes and **lock** your form again. Complete the assignment by selecting the appropriate status in the **Next Step/Decision** dropdown and finish by selecting **I am done**.

You can access your assignment via the link in this email, and also from RIMS via Human Ethics – Action Items.



This is an automatically generated communication from RIMS. Please do not reply to this email.

The email informs you of the important components relevant to your submission, including:

- what submission the communication relates to
- the status of the submission (i.e., what outcome or decision to you need to respond to in the example above this is "Pre-review feedback" to an initial application to the HREC)
- instructions on how to complete your assignment once you are logged into RIMS
- a web link directly to your assignment in RIMS (note: you will be prompted to login to RIMS once you click on this link.

Action Items

The workflow assignment notifications discussed above will always be accompanied by an entry within your RIMS **Action Items**. This means that for any workflow assignment, you will have two options of responding. The first is outlined above – further details on using Action Items follow below.

Upon logging into RIMS, click on the **Action Items** tab. This will display any outstanding assignment for any ethics protocol you currently have a role on, as shown in Figure 1.

Figure 1

RIMS				
Home My Profile	Locate My Records Locate Records Calendar Messages Action Items			
Research Grants	This set to do 20 the set			
	I nings to do - 3 items			
Human Ethics				
	H-2021-0039 (Human Ethics) - Pre-Review Feedback Initial Application			
Animal Ethics	Night and Day (Part 2) Name of CI will be displayed here			
My Projects	Action Item Assigned 10 minutes ago			
	H-2021-0038 (Human Ethics) - Admin Modifications Required I Variation			
SPIN	A room with a view			
	Action Item Assigned 7 days ago			
	Day 000507 (luman Ethics) Admin Madifestions Desuited Haifel Amiliation			
	Dev-008507 (Human Ethics) - Admin Modifications Required Initial Application			
	Vision Australia			
	Action Item Assigned 74 days ago			



Each assignment within your Action Items will display the following features:

- protocol management ID number
- status of your submission
- type of submission.

The name of the Chief Investigator for a protocol will also displayed as noted in Figure 1.

Action Items will remain on your list until the respective assignment is completed by either yourself or another member of the research team.

To access your workflow assignment, simply click on any part of the first line of the **Action Item** (the blue hyperlinked part).

Email Alert versus Action Item

Whether you access your workflow assignment from an **Email Link** or an **Action Item**, you will be directed to the assignment tab of your application eForm.

While the two options have the same function, we encourage you to familiarise yourself with working out of the **Action Items**. This method is likely a safer option, as an **Action Item** will never drop off if a member of the research team has not completed it. Whenever you look at your **Action Items**, you will only see what is outstanding. So, while the **Email Alert** may be effective as an notification that something needs to be attended to, the **Action Items** is a more stable reference point.

Completing your workflow assignment

When you enter the assignment from either an Email Link or an Action Item, you will be directed to the assignment tab of the application eForm. (See Figure 2)



Figure 2

4	Save Close Lock Form 🗹 🧏 Validate
THE UNIVERSITY OF NEWCASTLE AUSTRALIA	
Assignment	
Key Information ①	Your application to the HREC has received Pre-Review Feedback.
Researcher Details	1. Select Assign to Self if ready to action. Note that this will remove the assignment from the Action Items of other
Research Personnel Not Listed	Investigators named on the protocol.
Type of Research	2. To look at your Pre-review Feedback, open the Add or show comments screen, which is accessible from the main menu at the top of this screen. Respond to your Pre Peview Feedback
Research Population	3. Make any changes to your application/attachments as required. Note that you will need to unlock the eForm to make
Research Methods / Techniques	any changes to it.
Consent Process	 Save any changes made and lock your form again. Complete the assignment by selecting the appropriate status in the Next Step/Decision dropdown and finish by selecting I am done.
Research Sites	
Project Overview	You can access your assignment via the link in this email, and also from RIMS via Human Ethics - Action Items.
Participant Recruitment & ()	This is an automatically generated communication from RIMS. Please do not reply to this email.
Analysis and Reporting	
Data Management	
Attachments ①	Next Step/Decision: Select Step
Declaration	Assign to: Please select a Status
Form: Initial Approval Submission - New Project	
	Assign To Self

Review your assignment

Your assignment details will display any time you select the assignment tab within the eForm. From here, you will be able to see your submission's status together with a list of detailed instructions on how to finalise the assignment as shown in Figure 2.

Access feedback comments

To complete an assignment, the research team will need to access any feedback from the HREC/College Panel. This means considering and answering the feedback firstly and secondly, updating your application to reflect any changes made to the proposed research. Please see the **Comments Panel** User Guide for more detailed information on this process.

You can access the **Comments Panel** through the menu at the top of your eForm as shown in Figure 3.

Human Research Ethics RIMS User Guide

Completing Workflow Assignments



Figure 3



From here:

- click the menu option
- select the Add or Show Comments option.

Figure 4



You will now be able to view and respond to any feedback circulated. You can either:

- expand feedback per theme or
- expand all comment points.

All comments are viewable on the specific section of the eForm they pertain to also. The Comments Panel itself compiles these together for access in a single spot. We recommend using this feature for viewing/responding to comments.



Finalise the assignment

Once you have responded to any feedback with the comments panel and made any necessary changes to your application eForm, the next step is to finalise the assignment.

This will send the submission back to ethics administration. To finalise the assignment, ensure you are back on your **Assignment** tab (see Figure 5) and follow the steps outlined below.

Figure 5

Assignment
Your application to the HREC has received Pre-Review Feedback.
1. Select Assign to Self if ready to action. Note that this will remove the assignment from the Action Items of other Investigators named on the protocol.
To look at your Pre-review Feedback, open the Add or show comments screen, which is accessible from the main menu at the top of this screen. Respond to your Pre-Review Feedback.
Make any changes to your application/attachments as required. Note that you will need to unlock the eForm to make any changes to it.
 Save any changes made and lock your form again. Complete the assignment by selecting the appropriate status in the Next Step/Decision dropdown and finish by selecting I am done.
You can access your assignment via the link in this email, and also from RIMS via Human Ethics - Action Items. This is an automatically generated communication from RIMS. Please do not reply to this email.
Next Step/Decision: Select Step
Assign to: Select Step Response to Pre-Review Feedback Application Withdrawn
Assign To Self 1

1. Select the 'Assign to Self' option.

Only select this option if the assignment is ready to finalise. Selecting the **Assign to self** function will remove the assignment from the **Action Items** of any other researchers listed on the application.

We suggest that researchers who are *preparing* responses to the HREC/College Panel do not choose to **Assign to self**. Any preparatory work developed to responding to feedback can be undertaken without choosing this option. If no one **Assign to self**, the assignment will be available through the **Action Items** of all.



Once all feedback has been attended to and the eForm has been updated accordingly (if applicable), **Assign to self** should be selected. Note that the project Chief Investigator should be the only member of the research team to assign to self and finalise the assignment. If you are preparing a response and it is ready for the CI to review and potentially submit, please notify them.

2. Select the appropriate option within the Next Step/Decision section.

The options available to select will be determined by which status a submission is at. For example, the status of the above submission is at **Pre-Review Feedback**. To send it to have a response considered, **Response to Pre-review Feedback** needs to be selected. At any status there will only be two options to select: Either one to progress your application or another to withdraw it.

3. After the **Assign to self** option has been selected, the screen will change to highlight the **I am done** option, as shown in Figure 6. To finalise the assignment, select **I am done**. The assignment will now disappear from the **Action Items** of all researchers involved.

Figure 6

Assignment	
Your application	o the HREC has received Pre-Review Feedback.
1. Select Assign	to Self if ready to action. Note that this will remove the assignment from the Action Items of other
Investigators na	med on the protocol.
2. To look at your	Pre-review Feedback, open the Add or show comments screen, which is accessible from the main menu
at the top of this	screen. Respond to your Pre-Review Feedback.
3. Make any cha	nges to your application/attachments as required. Note that you will need to unlock the eForm to make
any changes to	it.
4. Save any char	iges made and lock your form again. Complete the assignment by selecting the appropriate status in the
Next Step/Decis	ion dropdown and finish by selecting I am done.
Next Step/Decisi	on: Response to Pre-Review Feedt 🗸
Assign to:	Automatic as per configurations.
l am done	

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 <u>human-ethics@newcastle.edu.au</u>.