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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 and variation requests. The pilot involves two of our three Colleges – the College of Health, Medicine and Wellbeing and the College of Human and Social Futures. Refer to the Human Ethics section of the <u>ReSearchHub</u> for more details.



Purpose of this guide

The RIMS configurations introduced in March 2022 allow you to respond to feedback from the Human Research Ethics Committee (HREC) or College-based review panels quicker and more easily than before.

Instead of drafting a response letter and creating a new 'Response' submission, you can now access your workflow assignment*, click on the link and prepare your response within the application eForm. This guide steps you through process of responding to reviewer feedback.

* See the RIMS User Guide – Completing Workflow Assignments for more detail.

Accessing the Comment panel

The Human Ethics Team can post review feedback against any question or attachment within an application eForm. The **Comment** panel consolidates this feedback and presents it in a single place. It also allows you to respond to all the feedback from the one place.

The **Comment** panel is accessible through the menu located at the top-right of your application eForm as shown in Figure 1. To access it:

- 1. Click on the Menu icon.
- 2. When the menu expands, select the **Add or Show Comments** option. This will prompt the **Comment** panel to display.



Figure 1



Comment panel features

When you open your Comment panel, it will display all current questions (and responses if any have been posted). To use this feature effectively, refer to Figure 2 and the supporting points below:

Figure 2

Comment Ascending	✓ Clear	Filter By:	🗸 🖌 Clear	Sort By:	✓ Dock	×
Expand All Comment Pe	3 Dints Collapse All C	omment Points				
Research des	sign <u>Comment</u>					
Inclusion / ex	clusion criteria	<u>Comment</u>				
2 What will par	ticipants be ask	ed to do? <u>Con</u>	<u>nment</u>			
U From: S	kene, Jarrod		To: Ethics Offi	ice - Cl/Co-Inv Group		
selected to appears th medical re 2. Also, it a Participant health reco	at the researcher we cord. appears that the ass for the researcher we cord. appears that the ass for the the second the s	creening involves ould not be able t essment mention ent (PIS) or the c be explained.	the use of the "Charl o establish unless the ed above does not at consent form even the	lson comorbidity index ey have access to the ppear to be mentioned ough it is related to the	" which patient in the patient	
 25-Oct-202 Potential risk Participant Ir 	1 02:52 PM Reply 5 (s <u>Comment</u> formation State	<u>Forward</u> ment(s) <u>Comm</u>	nent			

- 1. **Comment Point heading:** Feedback within the Comment panel is arranged within various headings (e.g., research design, potential risks, etc). These headings relate to either a question within the eForm or an application attachment (i.e., Participant Information Statement).
- 2. **Expand Comment Point:** Click on the arrow directly to the left of any Comment Point to expand it. Doing this will display the actual question or feedback from the HREC or College-based review panel.
- 3. **Expand/Collapse All Comment Points**: Use these buttons to expand or collapse all Comment Points in a single click.
- 4. **Comment Point Feedback:** Once expanded, the actual feedback for a respective point will be displayed. Note that there may be more than one question to address within a single comment point (as shown in Figure 2, item 4). Please ensure you review this content thoroughly.
- 5. **Reply:** Select the **Reply** function below any feedback you have received to respond to that feedback.



Once the **Comment** panel is open, you can move it to any area of your screen so you can review application content and feedback in the same window. To do this:

- 1. Maximise the window so you can see the expanded eForm display, as shown in Figure 3.
- 2. Open your Comment panel.
- 3. Drag the Comment panel to the right of screen so it no longer obscures content within the eForm. When arranged this way, you can scroll down the screen to review information and have Comment panel open on the side of the page for easy access.

Figure 3

		2 Save Close Lock Form	az ~
Key Information SAVE before ticking 'Lock Form' or closing the form, If 'Lock Form' i	is ticked, un-tick it to edit form.	Comment Ascending V Clear Filter By: V	✓ Clear Sort By: ✓ Dock
Human Research Ethics Committee		Expand All Comment Points Collapse All Comment Points	
Initial Approval Submission - New Project	THE UNIVERSITY OF NEWCASTLE AUSTRALIA	Research design <u>Comment</u> Surveys / questionnaire(s) <u>Comment</u> Head of School Declaration <u>Comment</u> Written informed consent <u>Comment</u>	
When to use this form			
This form is an Initial submission to the University of Newcastle (UON) Human F for approval for a new research project where the HREC is the lead committee.	esearch Ethics Committee (HREC)	3	
An Initial submission is the first application to the HREC for ethics approval for a Once approved, subsequent variations to the protocol may be proposed using an application form.	nis research project or activity. amended version of the initial		
Prior to submitting this application, it is recommended that you consult with a <u>Res</u> may accelerate the review process.	search Ethics Advisor (REA) as it		
I confirm I am applying for Initial approval for a new research project where committee.	the UON HREC is the lead		
OR			
l am applying for a variation to an existing protocol. 🗖			
Eligibility for Expedited Review			
The HREC applies a hierarchical level of review to submissions for efficie appro- and possible risks to research participants presented by the research protocol. M submissions are eligible for expedited review, whereas More than Low Risk sub- the potential for harm and require the completion of the Human Research Ethics this submission, and full HREC review.	al. This reflects the ethical issues egligible Risk and Low Risk missions are considered to have Application (HREA), in addition to		
Negligible Risk Research – describes research in which there is no foreseeable any foreseeable risk is no more than inconvenience. E.g. minor survey or intervie	risk of harm or discomfort, and w on a benign topic, giving up		

Responding to comments

The feedback you receive from the HREC, your College-based review panel or the Human Ethics Team can be responded to within the Comment panel. Responding to this feedback is a crucial part of the application process.

Once you have reviewed the feedback provided, respond in the Comment panel, amend any parts of your eForm that may need to be altered, and upload any new versions of existing attachments or new attachments within the Attachments tab.

To post a response to any comment in the Comment panel, refer to Figure 4.



Figure 4

omment Ascending V Clear Filter By: V Clear Sort By: V Doo
Expand All Comment Points Collapse All Comment Points
 Head of School Declaration Comment Image: Comment Comment Image: Comment Comment From: Skene, Jarrod To: Ethics Office - CI/Co-Inv Group Please provide a signed HoS Declaration. 30-Nov-2021 11:26 AM Reply. Forward
Skene, Jarrod ; Ethics Office - CI/Co- Inv Group Subject Head of School Declaration
Message
B I U abe E
add your comments

Select the **Reply** link below any comment, enter your response within the **Message** field, and select **Post** to finalise.

Any researcher listed on the application will have access to the Comment panel and can respond to the feedback provided.

If you are responding to more than one point, make this clear in the Message field or enter one response per point you wish to address.

Once a response has been posted, it will display as shown in Figure 5.



Figure 5

lead o	of School Declaration Comment
V F	From: Skene, Jarrod To: Ethics Office - CI/Co-Inv Group
Ple	ase provide a signed HoS Declaration.
30-1	lov-2021 11:26 AM <u>Reply</u> <u>Forward</u>
	A signed HoS Declaration has now been uploaded.
	10-Dec-2021 10:07 AM Reply Forward Edit Delete
	(2) (3)

If any feedback has not been responded to, a red exclamation mark will appear against that section, as shown in Figure 6.

Figure 6

Assignment
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



If any red exclamation marks remain, return to the Comment panel and complete the required responses. You can:

- 1. edit and re-post a reply as shown in Figure 5
- 2. delete a posted reply, also shown in Figure 5.

The workflow assignment cannot be finalised until **all** feedback has been responded to.

For questions or support

If you have questions about this guide or need additional support, please contact the Human Research Ethics team on <u>human-ethics@newcastle.edu.au</u>.

END of document