

ETHICS REVIEWER AND CHAIR USER GUIDE

This document will outline the responsibilities for ethics reviewers and chairs, and provide step-by-step guidance on how to conduct a review in the Ethics Online System for proportionate reviews (reviewer only), committee reviews (a.k.a. full reviews), and amendment reviews (chair only).

<u>Proportionate review.....</u>	<u>2</u>
<u>Committee review (a.k.a full review).....</u>	<u>9</u>
<u>IRAS and MLA applications</u>	<u>15</u>
<u>Amendment review.....</u>	<u>17</u>

HOW TO CONDUCT A PROPORTIONATE REVIEW IN THE ETHICS ONLINE SYSTEM (REVIEWERS ONLY)

A note on timelines: Proportionate reviews are permitted to take up to 20 working days from the date the reviewer is assigned to an application. This timeline is paused if/when the application is returned to the applicant for revisions.

Step 1: Log into the Ethics Online System

Follow this link to access the [Ethics Online System](#) – or navigate to the Reviewer portal from the [Ethics and Integrity webpages](#). You can also click on the system link in your notification email.

This will take you straight into your Work Area as the system uses your university details and single sign on.

The different tiles show applications at their different stages:

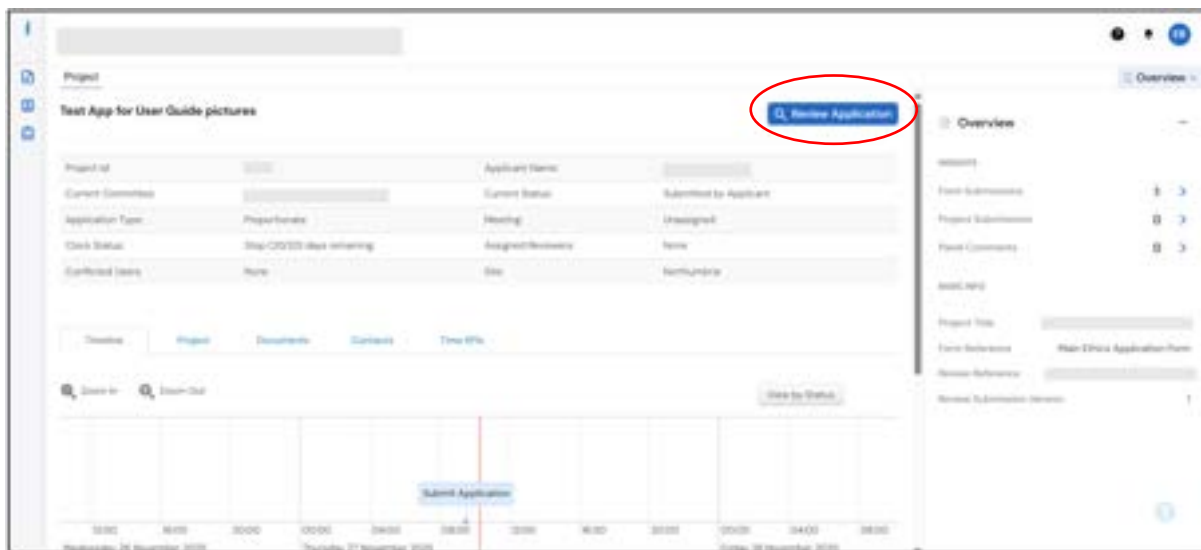
- ‘Notifications’ provide updates and actions required of you.
- ‘Review to complete’ show new applications
- ‘With applicant’ details applications which have been sent back to the applicant with revisions pending
- ‘Revisions to review’ are applications with actions required from yourself
- ‘Completed reviews’ is an archive of your completed reviews

Step 2: Accessing an application

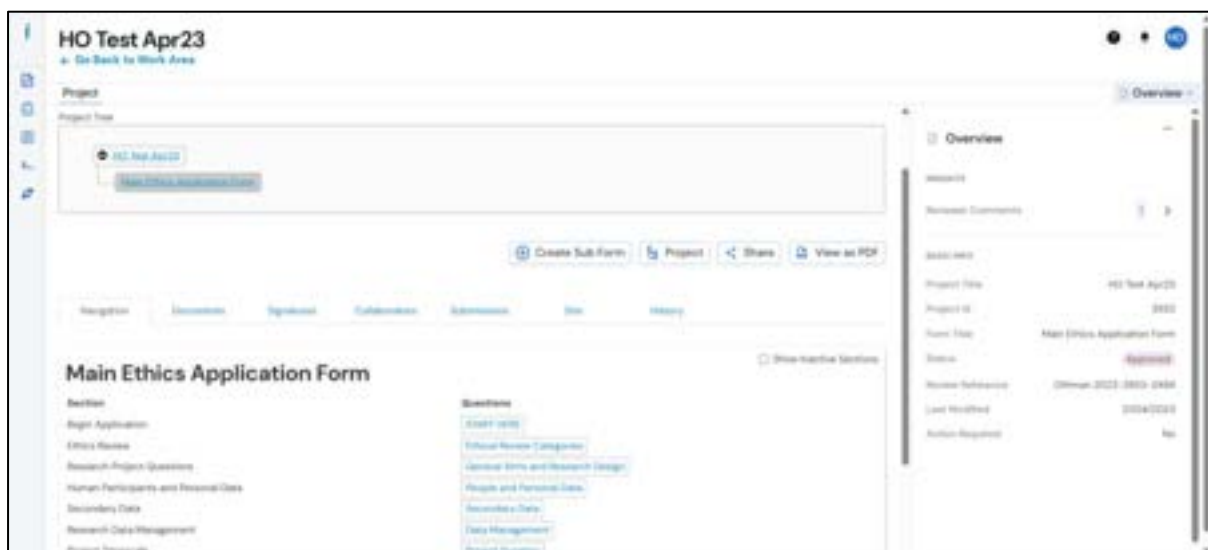
Click ‘Reviews to complete’ and this will show you the current reviews that have been assigned to you. New applications are highlighted in yellow, and you can tick to mark them as completed (just for your view) by clicking the tick on the far left column.

To open the application, just click on the project. This will take you to the Timeline page of the application where you can see some details like applicant name, reviewer names, faculty, and clock status (i.e. how many days are left to review).

You can also see the review type – whether this is proportionate or committee (aka. Full) review.



To start the review, click 'Review Application' in the Actions Bar in the centre of the screen. This will take you to the 'Navigate' page where you can see all the pages of the form. You can click on any of these to begin your review of the application.



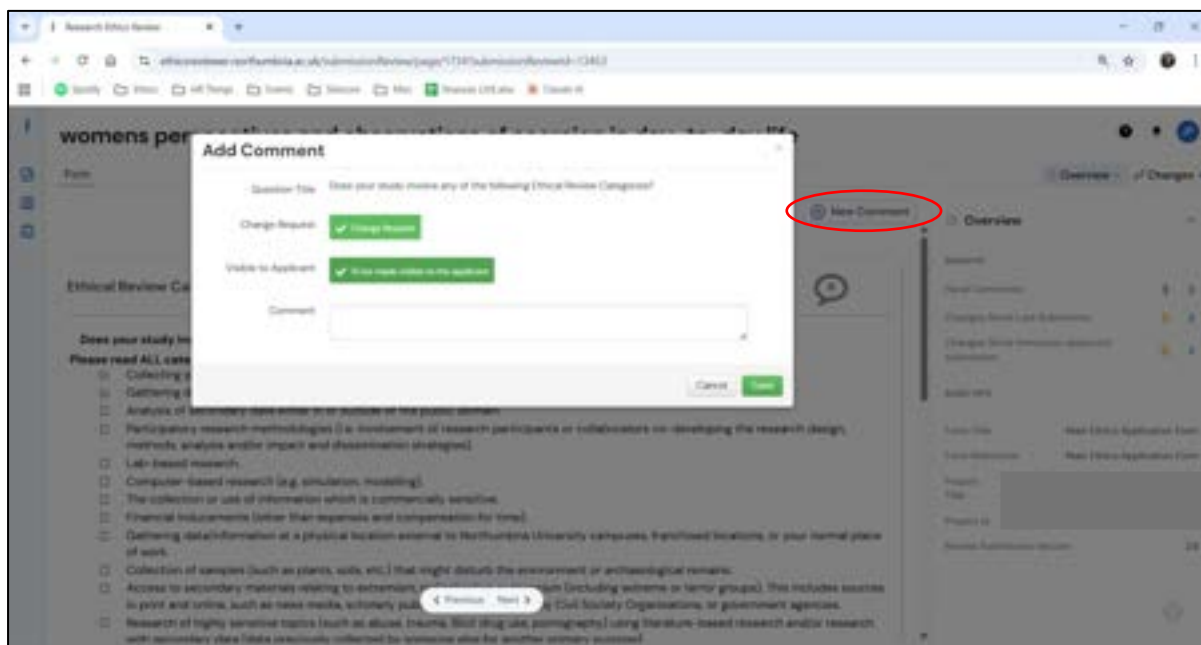
Step 3: Reviewing an application

Once inside the form, you can use the 'Previous' and 'Next' buttons at the bottom of the page, to flip through the pages. Alternatively, you can click on 'Navigate' in the Actions Bar and this will take you back to the list of page titles.



Step 4: Adding comments/revision requests

If you see a part of the application to which you want to ask for further information, clarification, or want to suggest a revision; on the relevant page, click on the 'New Comment' button in the Actions Bar in the centre of the page. Then, click on the section you want to attach the comment to, and then a pop-up will appear.



Type your comment or revision request into the box. Please also make sure that you click both of the greyed out boxes above the comment box to turn them green. This means the comments are now visible to the applicant. Unfortunately, the default is for them to invisible, so we need to ensure we are always clicking on both of these buttons.

Flagging issues or areas for improvement is the fundamental role of the reviewer, but please ensure that these are written in a tone that is respectful and constructive.

Step 5: Returning a decision

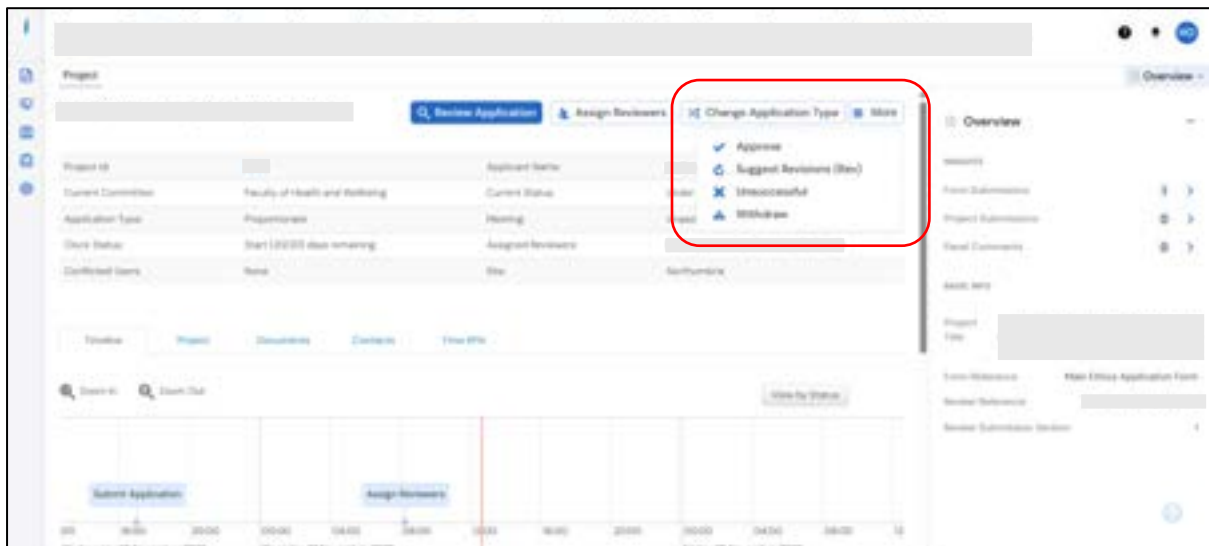
Once you're happy with the comments you have added (if any), click on the 'Timeline' button in the Actions Bar and this will take you back to the page where you started. Then click 'More' in the Actions Bar.

Proportionate application reviewers have three options here: 'Approve', 'Unsuccessful' or 'Suggest Revisions (Rev)'.

If you are happy with the application, select 'Approve' and this will confirm the application and send the approval letter to the applicant. This is the end of your role as a reviewer for this application.

If you have added comments, select 'Suggest Revisions (Rev)' and this will return the application to the applicant with actions for them to take.

If there are severe problems with the application that cannot be resolved, select 'Unsuccessful'. **However, please note** that once you reject an application, it cannot be reopened so we try not to use this button unless there are special circumstances. It is best practice to get a second opinion from the [AHoS RKE](#) if you feel like the application needs to be rejected altogether.

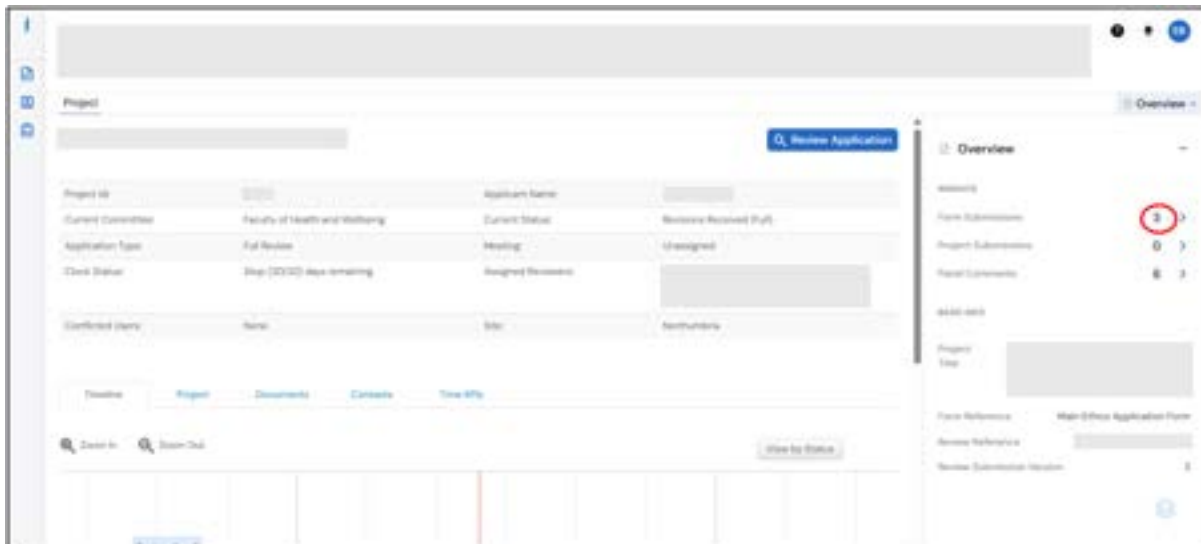


Step 6: After revisions have been made

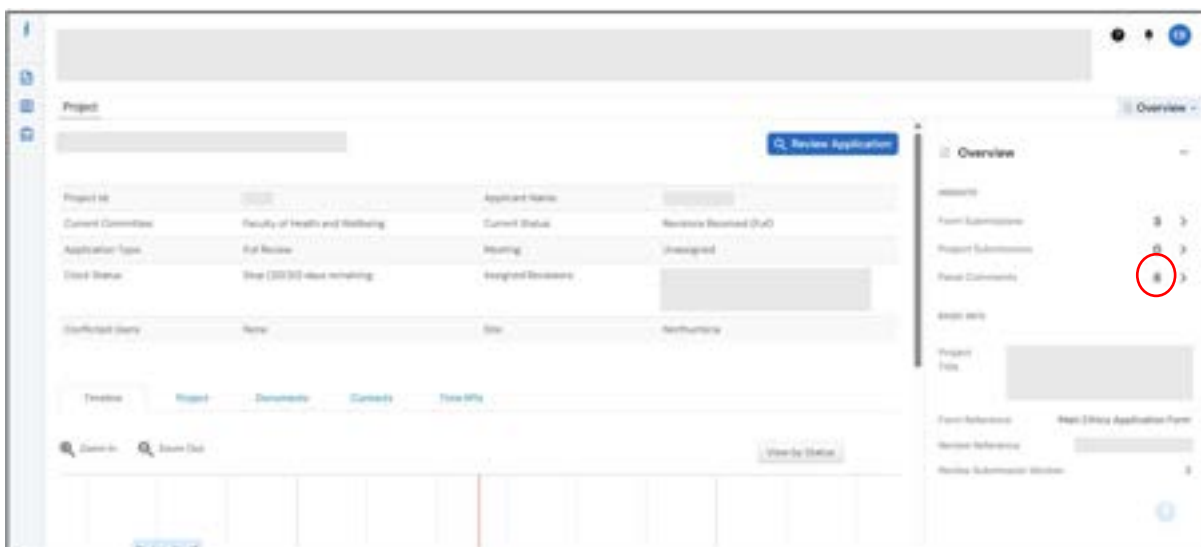
Once an applicant has made revisions, the reviewer then needs to review the application again. You can re-enter the reviewer portal in the same way as detailed in Step 1, or by clicking on the link in the notification email.

Then, in your Work Area, select 'Revisions to review', and open the application.

On the 'Timeline' page, you will be able to see that the system has created a new iteration of the form following the applicant's changes. You can click here to review the whole previous application, but you can also view the changes side by side on the new iteration as explained below.

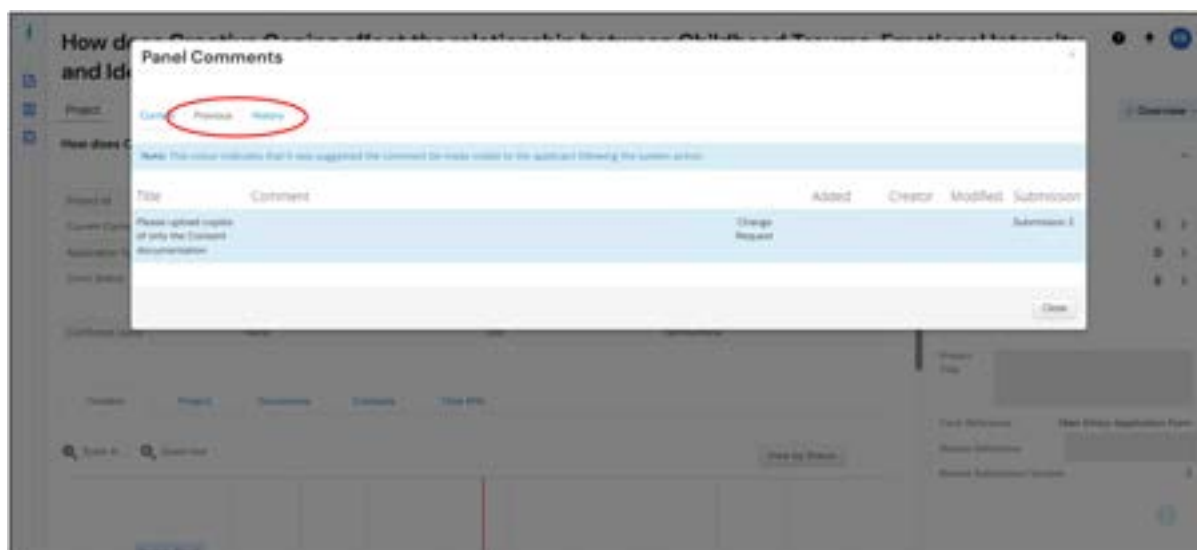


If you click on Panel Comments, you can view what has been said previously about the application – from either RIS or the reviewer.



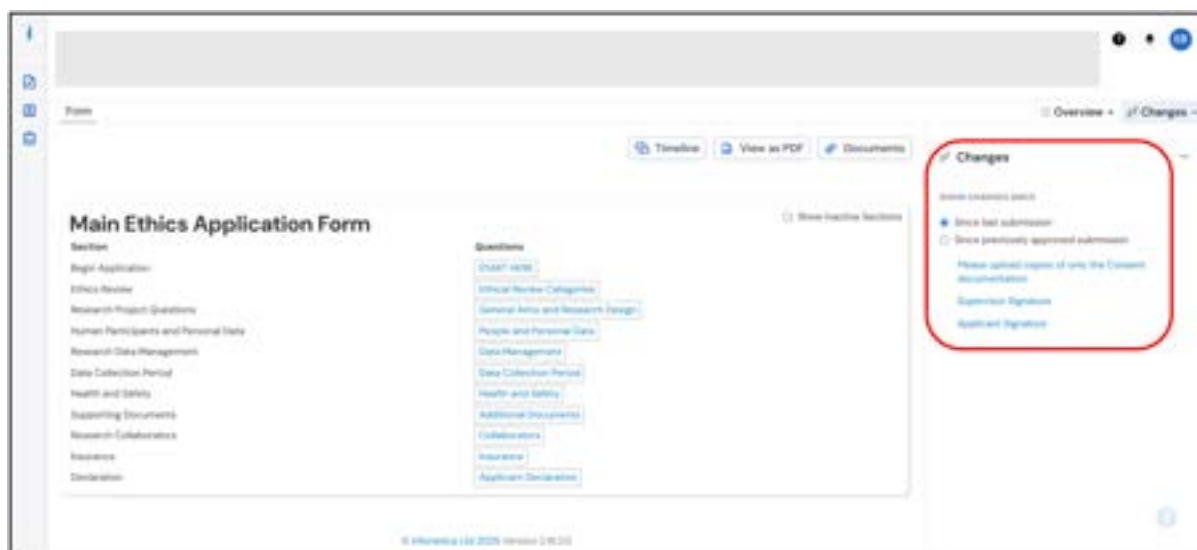
Initially, you might not see any comments if there aren't any attached to the current version of the form, but if you click on 'Previous', you can see comments from the previous submission and if you click 'History' you can see older comments too.

You can click on the question title to jump to the new answer.

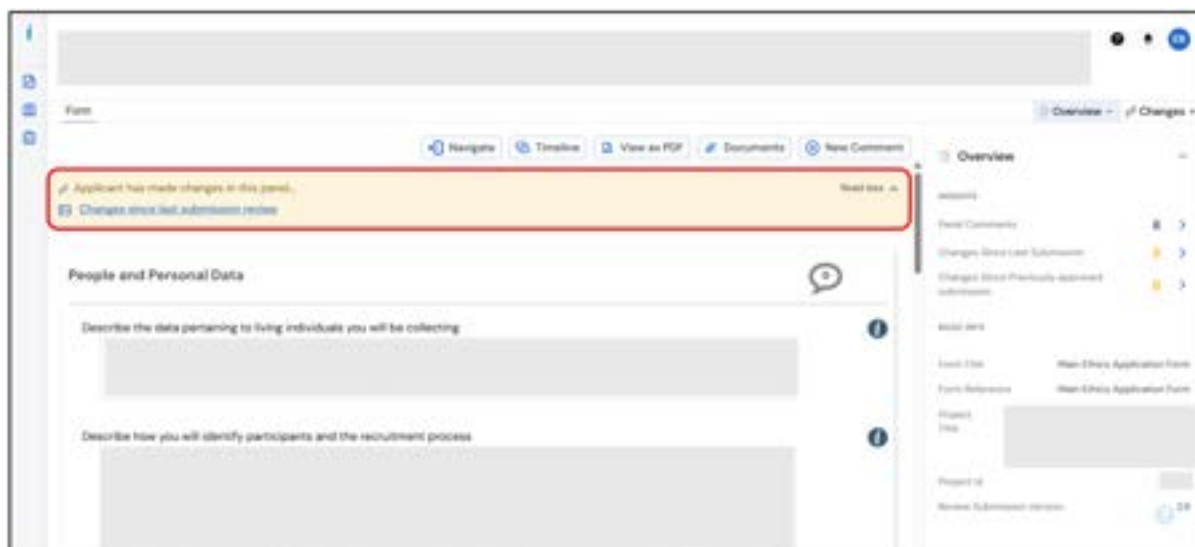


To view the changes side by side, click 'Review Application' and from the Navigate page you can either move through the form in the same way as previously outlined, or you can jump directly to the changes.

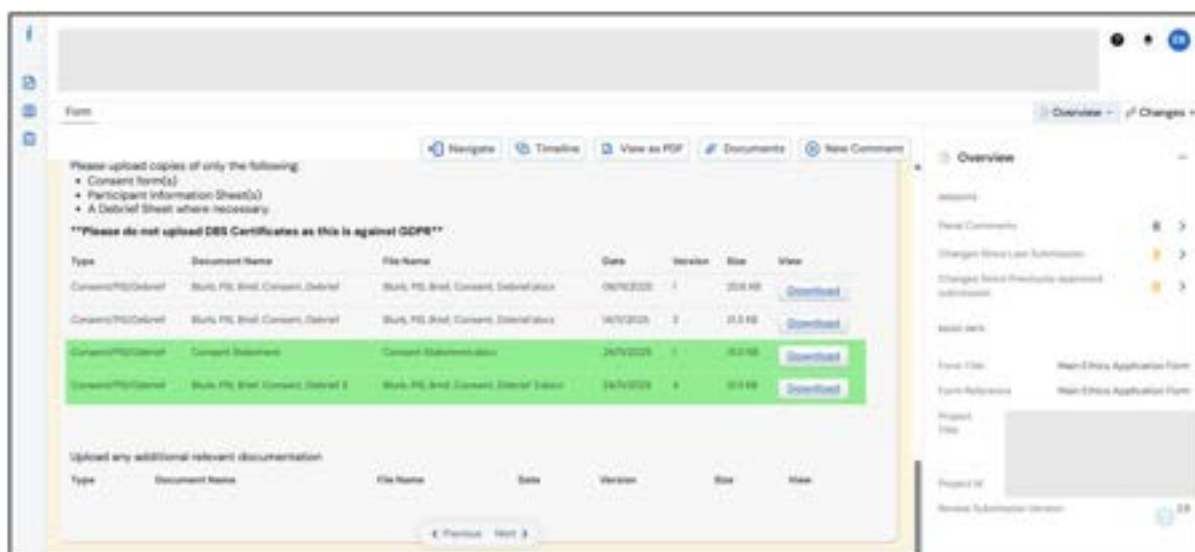
If you click 'Changes' in the tab next to 'Overview', it will highlight where revisions have been made. You can click on the question titles to jump straight to that answer.



On pages where changes have been made, at the top, there will be a yellow banner. If you click 'Read more' and then 'Changes since last submission review' you will be able to see the revisions side by side.



Any text or attachments that have been deleted show up in red, and any text or attachments that have been added show up in green.



Your role here is to ensure that the applicant has addressed all your comments and concerns and the application is now ready to approve.

If they have made the relevant revisions, you can approve the application as detailed in Step 5.

If they have not responded to one or more of your comments, please feel free to send it back to them again in the same way as outlined in Step 5.

Step 7: Once completed

Once the application has been approved, it will show on the Timeline page under 'Current Status' as approved and the application will receive their approval letter.

HOW TO CONDUCT A COMMITTEE REVIEW (A.K.A FULL REVIEW) IN THE ETHICS ONLINE SYSTEM (REVIEWERS AND CHAIR)

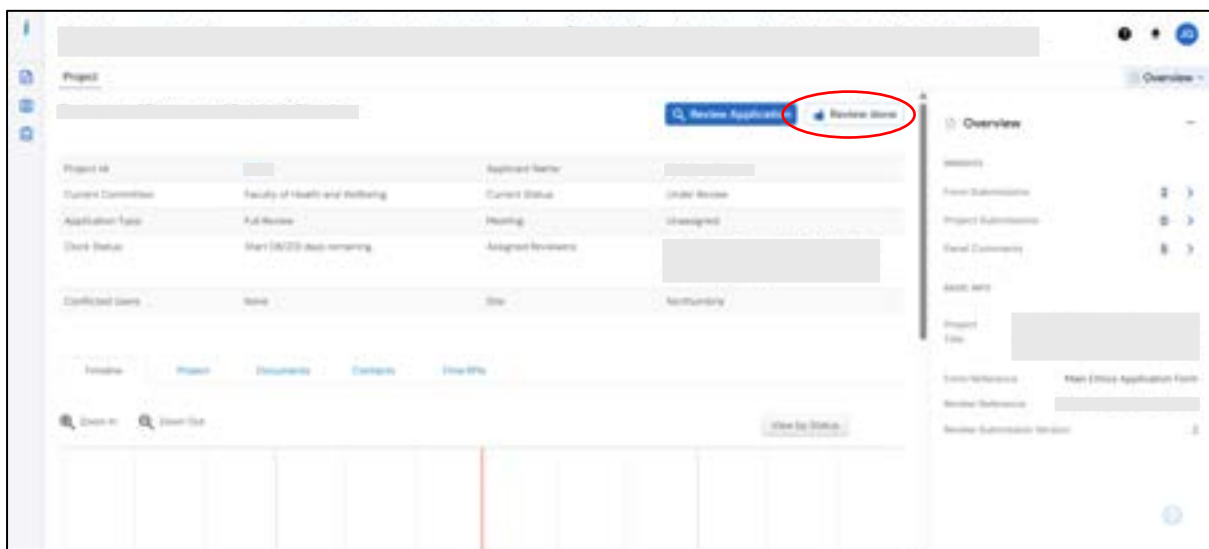
A note on timelines: Committee reviews (a.k.a. full reviews) are permitted to take up to 20 working days from the date the reviewer is assigned to an application. This timeline is paused if/when the application is returned to the applicant for revisions.

Reviewers, follow Steps 1-4 as outlined above

Step 5: Returning a decision

Once you're happy with the comments you have added (if any), click on the 'Timeline' button in the Actions Bar and this will take you back to the page where you started.

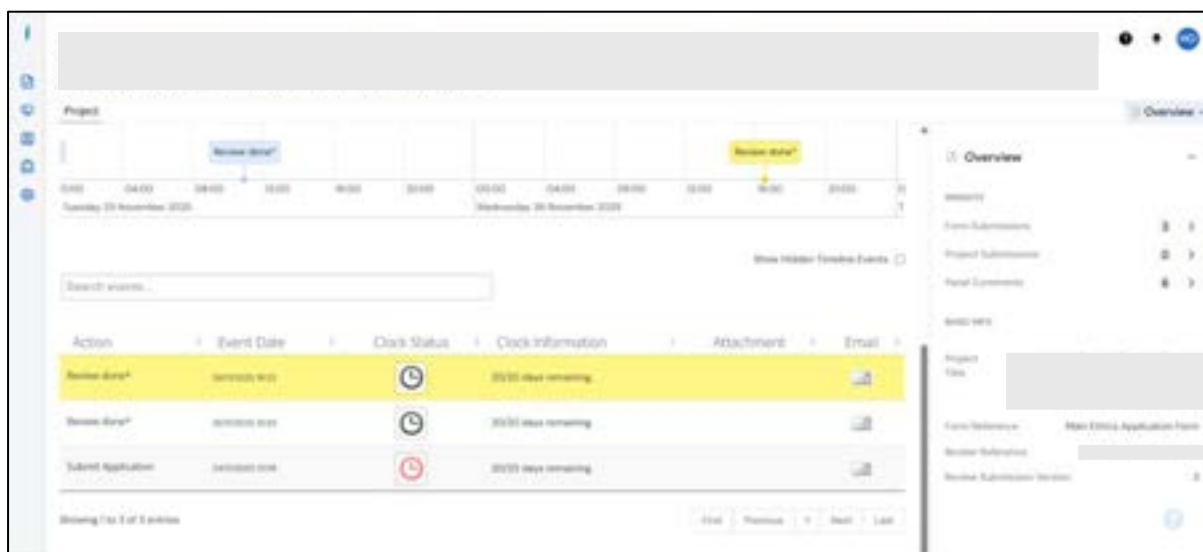
At this stage, reviewers have one option: 'Review done'. When you click this, it will ask you for a Timeline comment (where you can say something like "Revisions required" or "Happy to approve") and it will mark your part of the review as 'Review done'. You do not have the same permissions as proportionate reviewers because you are part of a committee review.



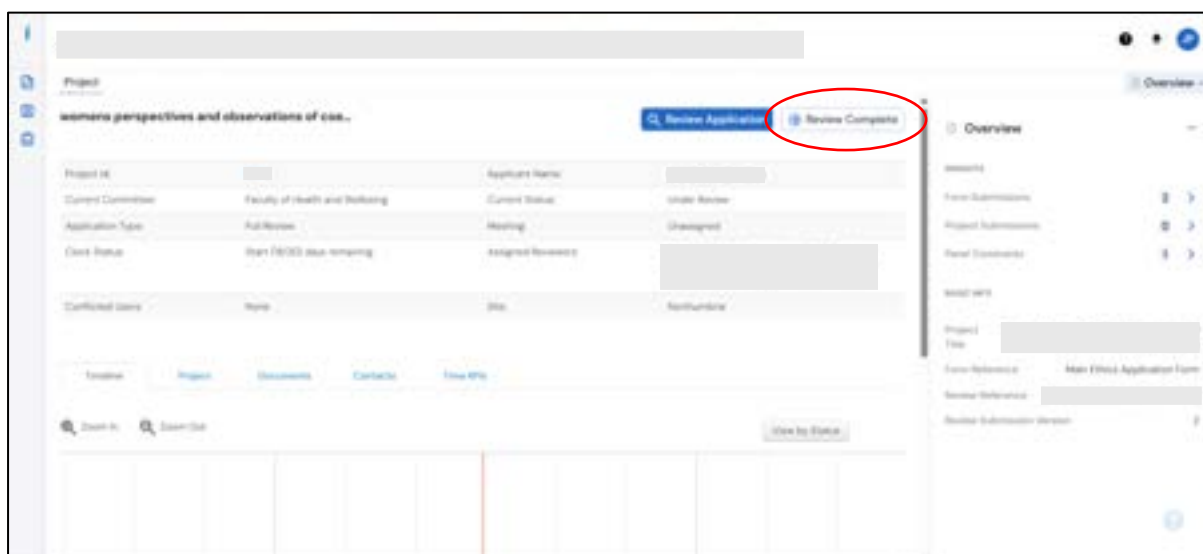
The application will remain in your Work Area under 'Reviews to complete' until the chair moves the application along. You can't remove this, but you can tick to mark them as completed (just for your view) by clicking the tick icon on the far left column.

The chair will receive system and email notifications letting them know that an application they are chairing has had a reviewer click 'Review done'.

From the Timeline page, the chair needs to click on the two 'Review done' actions (clock icon under 'clock status') to check that these have been performed by the two different reviewers. This information is also included in the notification email.



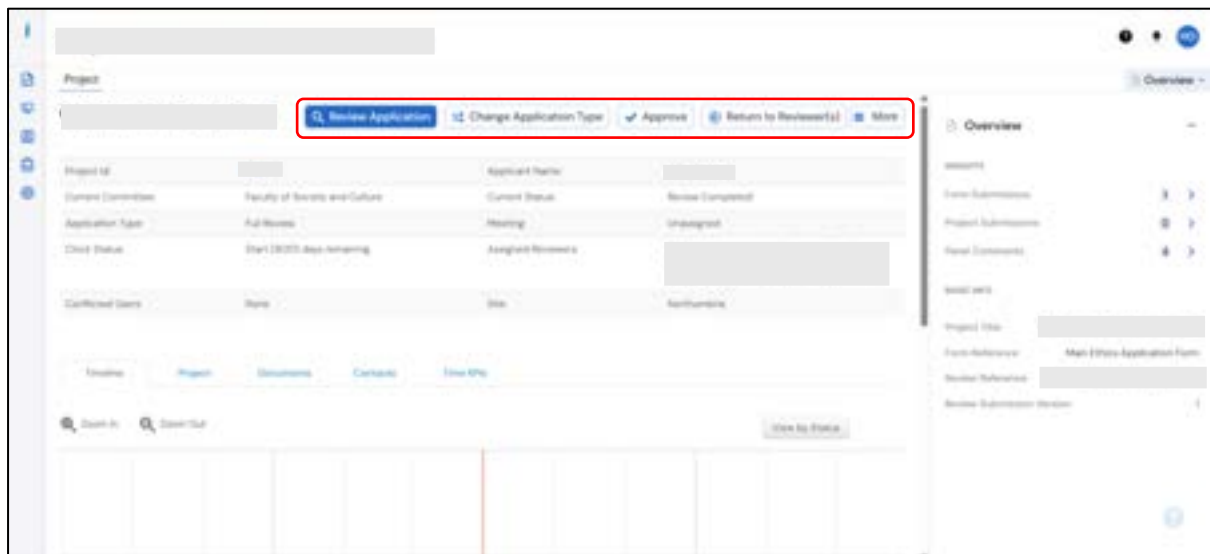
The chair then clicks on 'Review complete', bringing the application into their Work Area and out of the reviewers' work areas.



From the Timeline page, the chair needs to click 'Review Application' and undertake their own review of the application and the reviewers' comments. They have editing permissions to edit or delete reviewer comments, too. To view these, click 'Panel Comments' under the 'Overview' tab on the right hand side.

Once this is done, the chair needs to return to the Timeline page and then decide to 'Approve', 'Suggest Revisions (CHR)' or select 'Unsuccessful' (under 'More').

However, please note that once you reject an application, it cannot be reopened so we try not to use this button unless there are special circumstances.



If the chair is happy with the application, select 'Approve' and this will confirm the application and send the approval letter to the applicant. This is the end of the reviewing process for this application.

If there are added comments that need addressing, click 'More' and then select 'Suggest Revisions (CHR)' and this will return the application to the applicant with actions for them to take.

If there are severe problems with the application that cannot be resolved, select 'Unsuccessful' (under 'More'). **However, please note** that once you reject an application, it cannot be reopened so we try not to use this button unless there are special circumstances.

There is also the option to return the application to the reviewers, should this be needed.

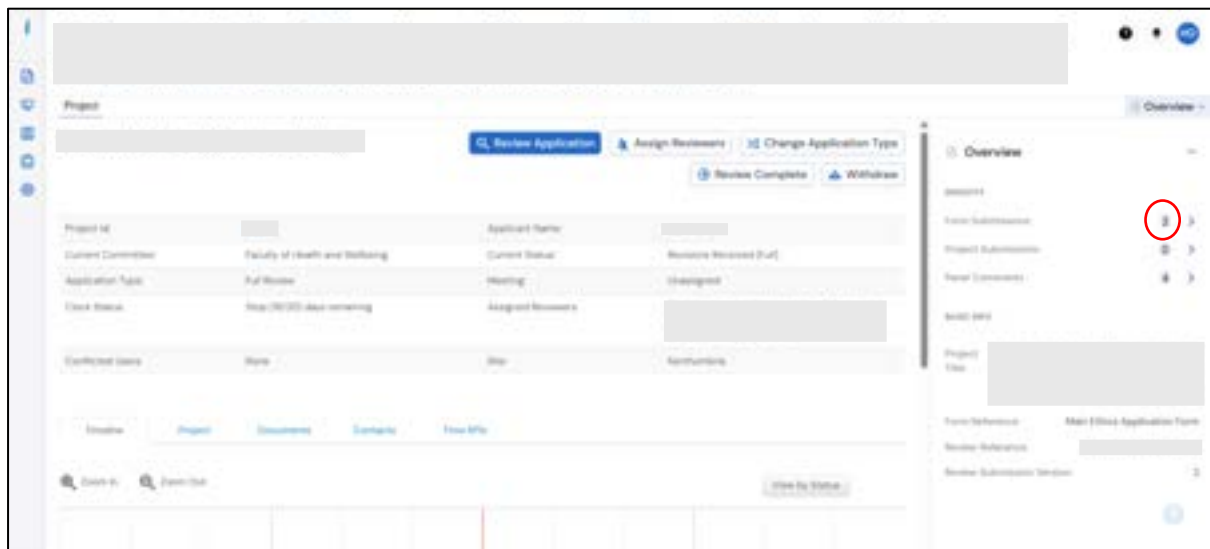
Step 6: After revisions have been made

Once an applicant has made revisions, the application will be returned to the reviewers.

Reviewers can re-enter the reviewer portal in the same way as detailed in Step 1, or by clicking on the link in the notification email.

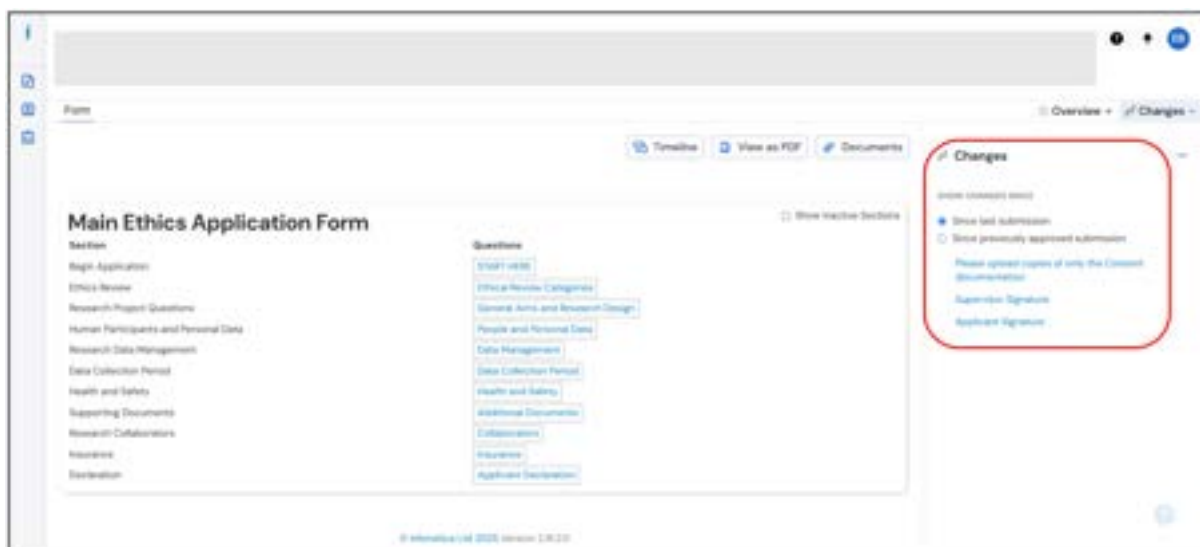
Then, in your Work Area, select 'Revisions to review', and open the application.

On the 'Timeline' page, you will be able to see that the system has created a new iteration of the form following the applicant's changes. You can click here to review the whole previous application, but you can also view the changes side by side on the new iteration.



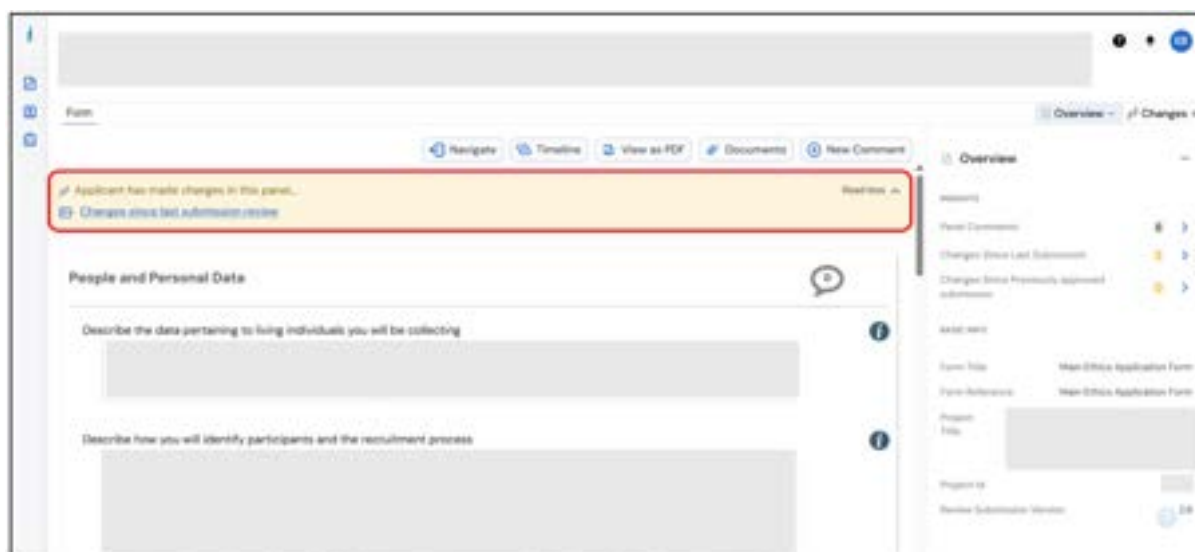
Next, click 'Review Application' and from the Navigate page you can either choose a page to view, use the Actions Bar to move through the form in the same way as previously outlined, or you can jump directly to the changes.

If you click the 'Changes' tab next to 'Overview' on the right hand side, it will highlight where changes have been made. You can click on the question titles to jump straight to that answer.

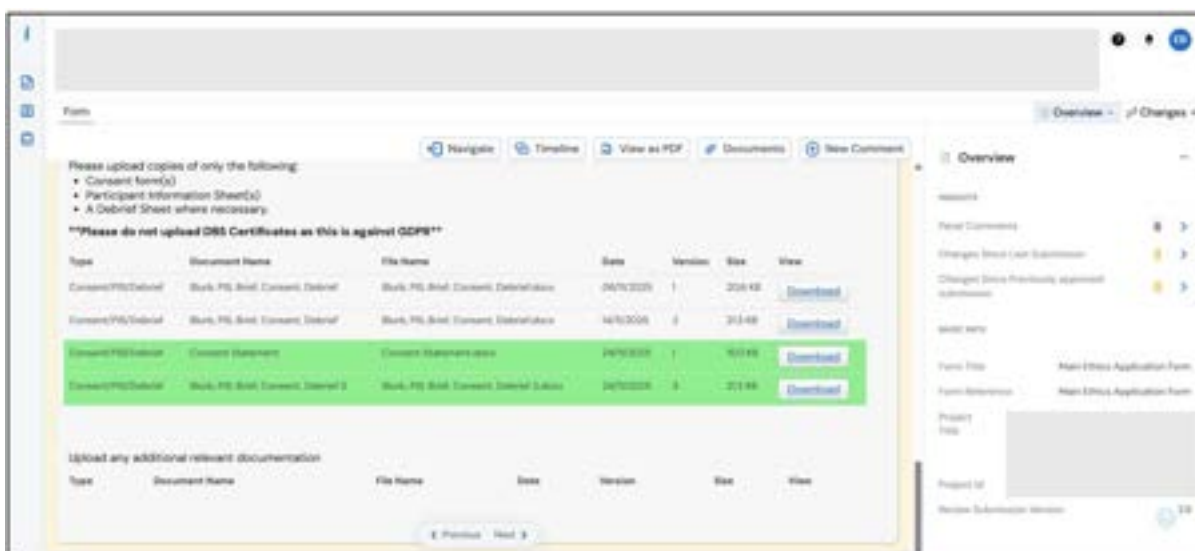


You can also click 'Panel Comments' under 'Overview' to see previous comments and also click to jump straight to those questions to see if the appropriate changes have been made. You will need to click 'Previous' to see the comments attached to the previous/original version of the application.

On pages where changes have been made, at the top, there will be a yellow banner. If you click 'Read more' and then 'Changes since last submission review' you will be able to see the revisions side by side.



Any text or attachments that have been deleted show up in red, and any text or attachments that have been added show up in green.



Your role here as the reviewer is to ensure that the applicant has addressed all your comments and concerns and that the application is now ready to approve.

If they have made the relevant revisions, you can select 'Review done' and add a Timeline comment to say you are happy to approve as detailed in Step 5.

If they have not responded to one or some of your comments, please feel free to add more comments and suggest that it is sent it back to them again in the same way as outlined in Step 5.

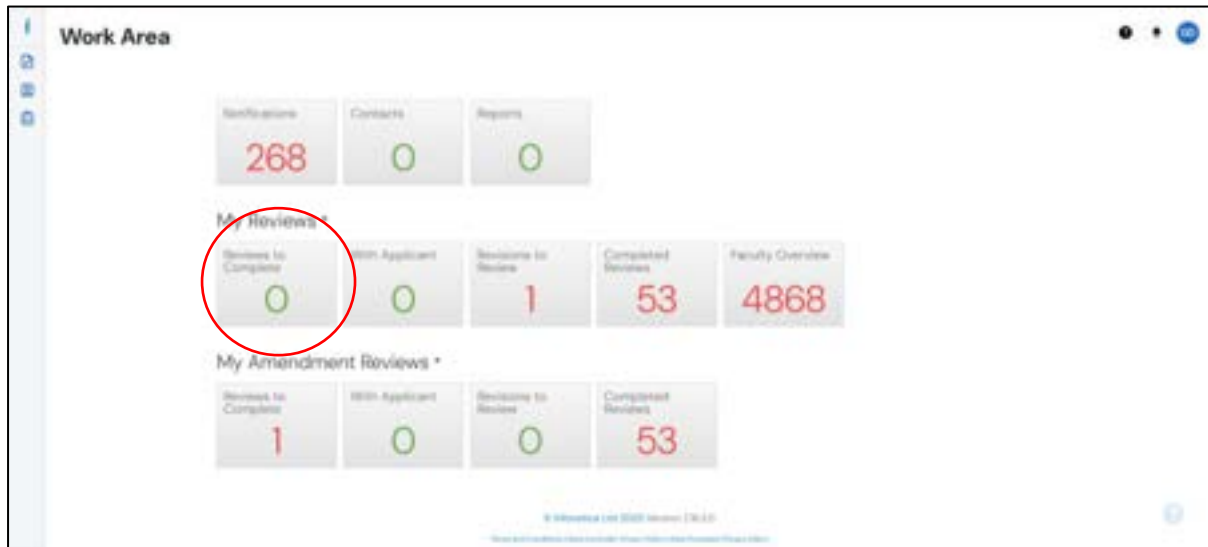
The chair, upon receiving the two 'Review done' notifications, will then return a final decision to 'Approve' or mark as 'Unsuccessful'. **However, please note** that once you reject an application, it cannot be reopened so we try not to use this button unless there are special circumstances.

Step 7: Once completed

Once the application has been approved, it will show on the Timeline page under 'Current Status' as approved and the application will receive their approval letter.

REVIEWING NU IRAS AND MLA APPLICATIONS

Both NU IRAS and MLA applications will appear in the normal work area tiles under 'Reviews to Complete'.



When you view the list of applications, you can see the application type under 'Submitted Form Reference'.

[pic of yellow applications list w new column titles]

Staff MLA Applications will always require proportionate level review, and are always reviewed by the Chair.

The chair can access and navigate the application as outlined in [steps 1-5](#).

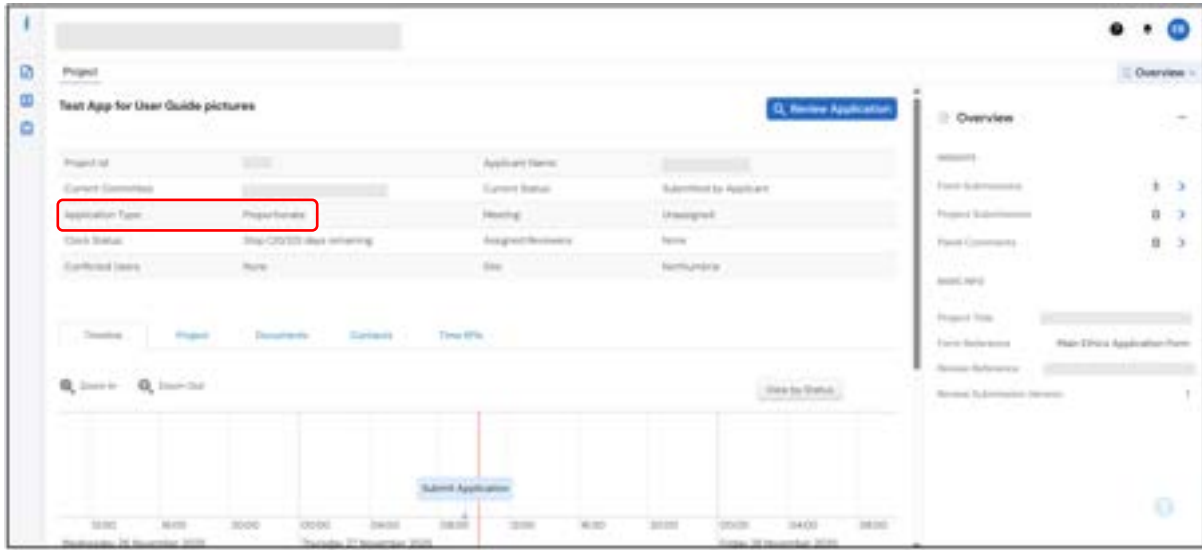
NU IRAS Applications may either require proportionate or committee (a.k.a. full) review, and can be assigned to both reviewers and chairs, depending on the review level.

For NU IRAS applications that have received NHS REC (Research Ethics Committee) approval, they will be approved centrally by the Ethics and Integrity Team in RIS.

For NU IRAS applications that have not received NHS REC approval (e.g. have only received HRA (Health Research Authority) approval), they will need to be reviewed and approved by the College of Reviewers, and the Chair if relevant to the review level.

If an IRAS application goes out to review, it can be accessed, navigated, reviewed, and approved in the same ways outlined in [steps 1-5](#) for either the proportionate or committee review pathway.

Reviewers and Chairs can see the review level for each application on the Timeline page next to 'Application Type' as highlighted below.



Project
Test App for User Guide pictures

[Review Application](#)

Project ID	Applicant Name
Current Committee	Current Status
Application Type Proprietary	Meeting Unassigned
Work Status: Stop (12/20) - Has Interviewing	Assigned Reviewers None
Confidential Status: None	Site: Northumbria

Overview | **Project** | Documents | Contact | Time Mfg.

Submit Application

Overview

- Event
- Form Submissions
- Project Submissions
- Form Comments
- Project Stop
- Form Reference
- Review Reference
- Review Submission Review

HOW TO CONDUCT AN AMENDMENT REVIEW (CHAIR ONLY)

A note on timelines: Amendment reviews are permitted to take up to 10 working days from the date the reviewer is assigned to an application. This timeline is paused if/when the application is returned to the applicant for revisions.

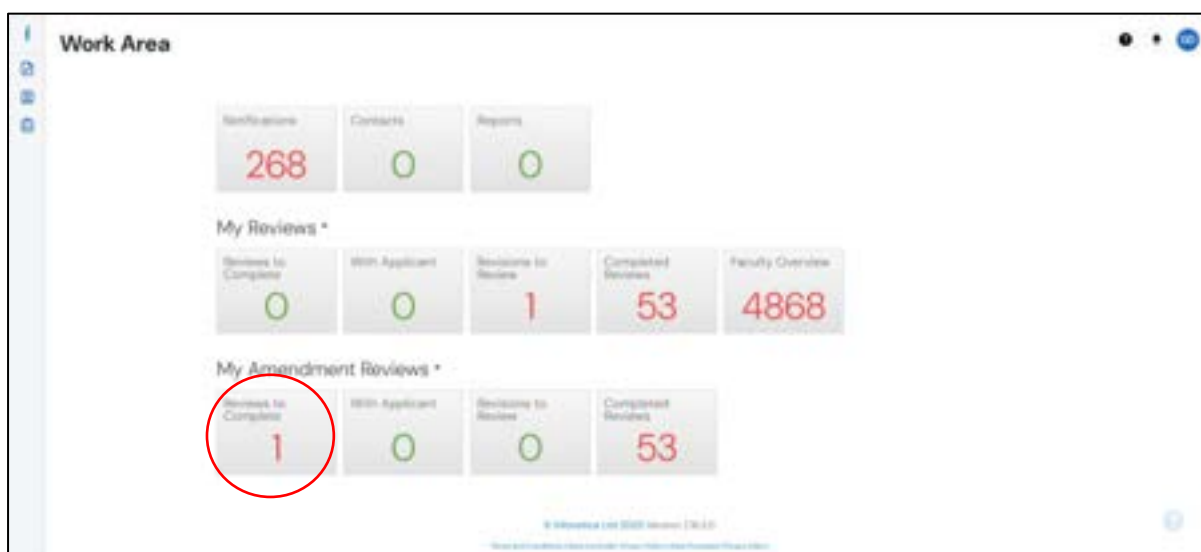
Step 1: Log into the Ethics Online System

Follow this link to access the [Ethics Online System](#) – or navigate to the Reviewer portal from the [Ethics and Integrity webpages](#). You can also click on the system link in your notification email.

This will take you straight into your Work Area as the system uses your university details and single sign on.

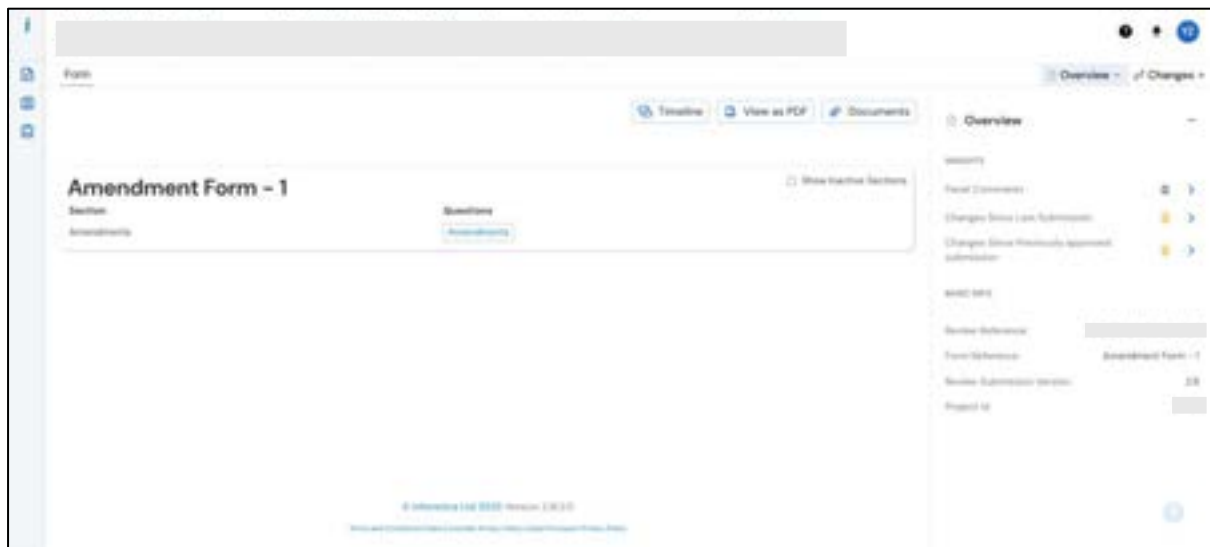
Step 2: Accessing an application

Under 'My Amendment reviews', click 'Reviews to complete' and this will show you the new applications which have been assigned to you.



Click on the application you wish to review to open it. This will then take you to the Timeline page.

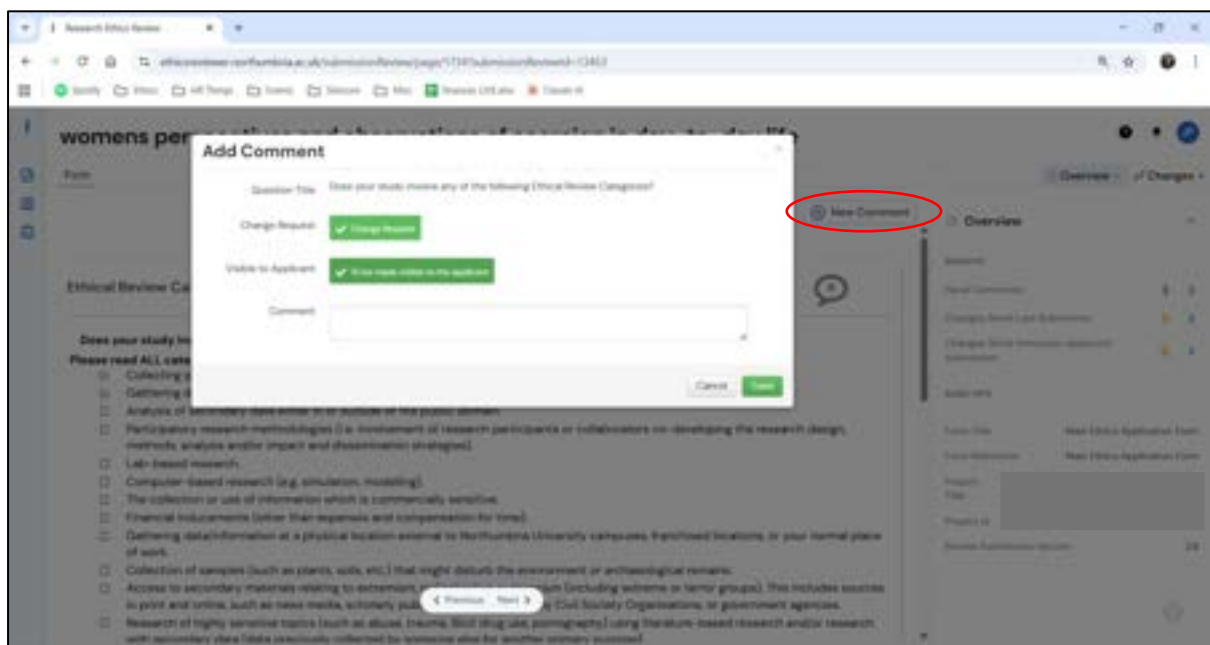
From here, in the Actions Bar click 'Review application'. There is only one page title as this is a single page form. Click on 'Amendments' to view.



Here you can see the original project title, a description of the amendment, the reason for this, and any ethical implications, as well as any attachments.

Step 3: Adding comments/revision requests

If you see a part of the application to which you want to ask for further information, clarification, or want to suggest a revision; on the relevant page, click on the 'New Comment' button in the Actions Bar in the centre of the page. Then, click on the response you want to attach the comment to, and then a pop-up will appear.



Type your comment or revision request into the box. Please also make sure that you click both of the greyed out boxes above the comment box to turn them green. This means the comments are now visible to the applicant. Unfortunately, the default is

for them to invisible, so we need to ensure we are always clicking on both of these buttons.

Flagging issues or areas for improvement is the fundamental role of the reviewer, but please ensure that these are written in a tone that is respectful and constructive.

Step 4: Returning a decision

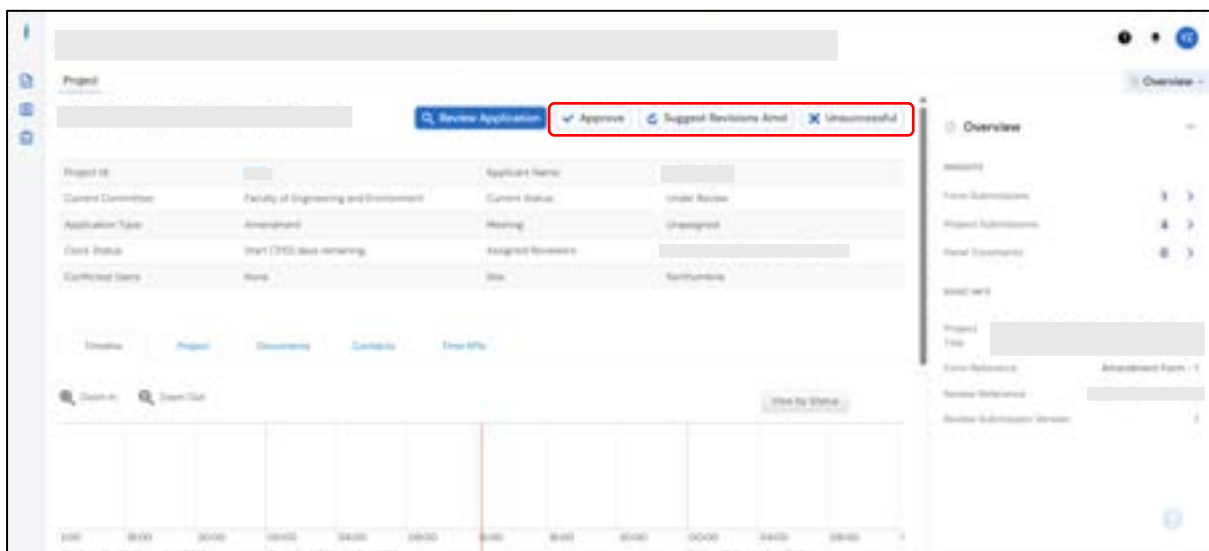
Once you're happy with the comments you have added (if any), click on the 'Timeline' button and this will take you back to the page where you started.

Amendment reviewers have three options in the Actions Panel: 'Approve', 'Unsuccessful' or 'Suggest Revisions (Amd)'.

If you are happy with the application, select 'Approve' and this will confirm the amendment application and send the approval letter to the applicant. This is the end of your role as a reviewer for this application.

If you have added comments, select 'Suggest Revisions (Amd)' and this will return the application to the applicant with actions for them to take.

If there are severe problems with the application that cannot be resolved, select 'Unsuccessful'. **However, please note** that once you reject an application, it cannot be reopened so we try not to use this button unless there are special circumstances.

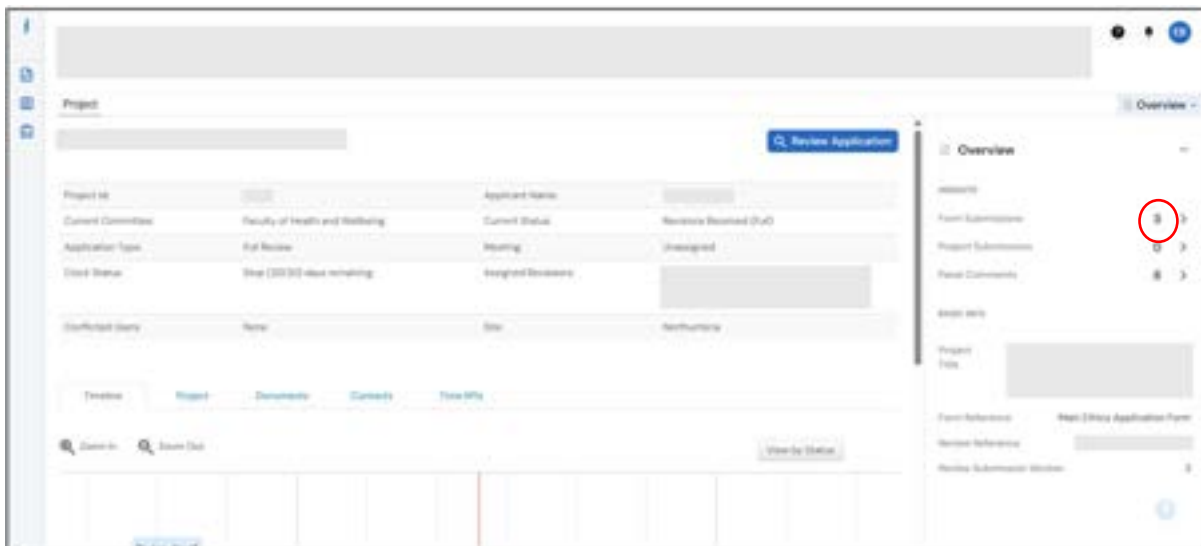


Step 5: After revisions have been made

Once an applicant has made revisions, the reviewer then needs to review the application again. You can re-enter the reviewer portal in the same way as detailed in Step 1, or by clicking on the link in the notification email.

Then, in your Work Area, under 'My Amendment Reviews', select 'Revisions to review', and open the application.

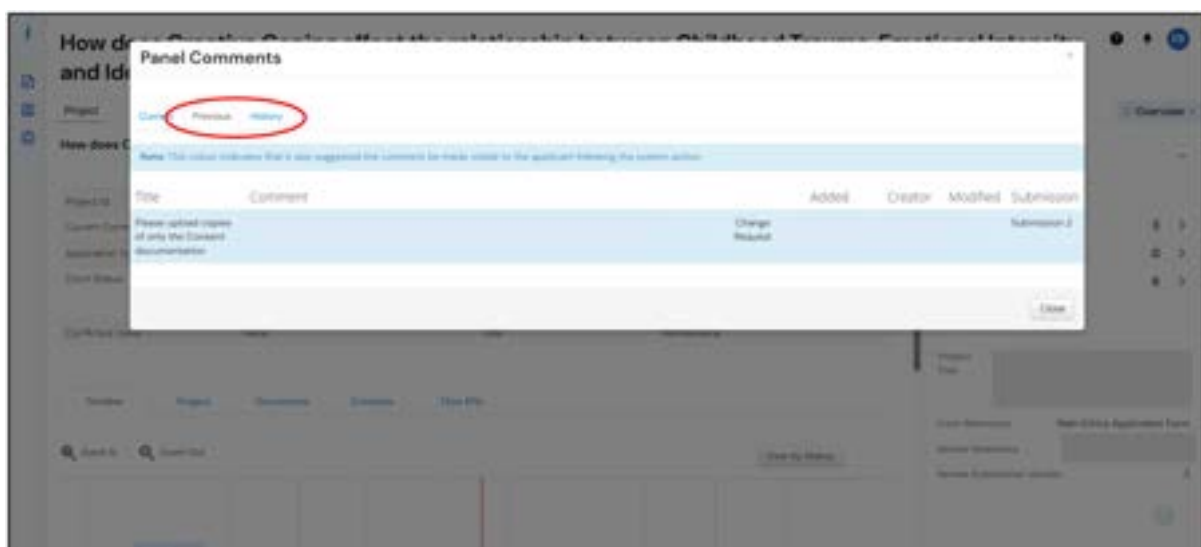
On the 'Timeline' page, in the Overview section on the right, you will be able to see that the system has created a new iteration of the form following the applicant's changes. You can click here to review the whole previous application, but you can also view the changes side by side on the new iteration.



Next, click 'Review Application'.

If you click 'Changes' in the tab next to 'Overview' on the right hand side, and it will highlight where revisions have been made. You can click on the question titles to jump straight to that answer.

Under the 'Overview' tab, you can also click 'Panel Comments' to see previous comments and also click to jump straight to those questions to see if the appropriate changes have been made. You will need to click 'Previous' to see the comments attached to the previous/original version of the application.



Step 7: Once completed

Once the application has been approved, it will show on the Timeline page under 'Current Status' as approved and the application will receive their approval letter.

For further support, please consult the [Ethics and Integrity webpages](#) which include contact information, other user guides, and answers to frequently asked questions.