## **REAMS Guidance for Reviewers**

## Contents

Ι.	Log	; In:	2
2.	The	General System of REAMS	2
	2.1	Introduction	2
	2.2	Two different workspaces: "on the form" and "in the form"	4
	2.2	1 Working on the application form:	4
	2.2	2 Working in the application form:	4
3.	Ove	erview pages	4
	3.1	Work Area	4
	3.2	Timeline overview	5
	3.3	Navigation overview (outer shell of the application)	6
	3.4	Inside the application (in the application form)	7
	3.5	Actions Box	8
4.	Rev	riew an Application	8
	4.1	Start by signing into REAMS with your name and password	8
	4.2	Start through invitation to review	9
	4.3	Navigation overview and Actions box	9
	4.4	Start reviewing (work inside the application form)	9
	4.5	Add comments	11
	4.6	Read and comment on uploaded documents	12
	4.7	Finishing your review – Sending Comments to the Lead Reviewer	15
	4.8	Close Comments by Lead Reviewer:	17
5.	Cor	nments closed – what next:	18
	5.1	Options for the Lead Reviewer	18
	5.2	Return to Applicant	22
	5.3	Applications back for Re-review - Changes	23
	5.4	Comments from the previous round of review	26
	5.5	Approval of Application	27
6.	Fur	ther Functions	29
	6.1	Notifications	29
	6.2	Panel comments	31
	6.3	Print	31
	6.4	Tips for reviewing applications as a pdf	32
	6.5	Tips for reviewing applications with pdf/word document attachments	33
	6.6	Screen does not show the Work Area tab or Actions buttons	33

### 1. Log in:

The <u>Research Ethics Application Management System</u> (REAMS) program from Infonetica consists of two different sides, namely the applicant side (called Forms) and the review/management side (called Review, this includes the roles of Reviewer/Lead Reviewer, Chair and Research Ethics Officer), each with its own separate login.

Whilst REAMS runs on several web browsers, we recommend that you use Google Chrome for the best user experience.

1) Log in for the applicant side (FORMS): https://reams.lancaster-

university.uk/ActivityForm/Index

Login name: your e-mail address

Password: Lancaster1 (or your personal password in case you have changed it)

2) Log in for the reviewer side (REVIEW): <a href="https://reams-review.lancaster-">https://reams-review.lancaster-</a>

university.uk/WorkArea/Index

Login name: your e-mail address

Password: Lancaster1 (or your personal password in case you have changed it)

## 2. The General System of REAMS

#### 2.1 Introduction

A video tutorial for reviewers in REAMS is currently being developed and will be made available soon.

- a) Application form: In REAMS all the questions that used to be part of the ethics application form are now inbuilt in the system. The program leads you from one question to the next, and only those questions and functions in the system that are relevant to the current application/project are shown.
- b) Attachments: The parts of the ethics application that were additional files until now, such as Participation Information Sheet (PIS), Consent Form, Questionnaires, Invitations etc. will stay as separate files and will be uploaded onto the system as Word/pdf/Excel files. Please note that all comments from reviewers will need to be in the REAMS form itself. While there is an option to add "sticky notes" onto attached pdf or comments into an attached word document, it is important that you also mention these comments inside the REAMS form so that these comments do not become 'lost' (Section 4.5).

c) Different reviewers: The REAMS system works with two levels of reviewers: Reviewers and Lead Reviewers. REAMS will inform you if you have been assigned as the application Reviewer or Lead Reviewer. Multiple reviewers can be assigned to each application simultaneously, such as members of a Faculty Ethics committee if an application is to be discussed during a meeting. All reviewers, as well as the Research Ethics Officer (REO) and the FREC Chair, can add comments. However, there is always only one Lead Reviewer, who will close the review process and send the application back to the applicant or forward it to the chair with the recommendation that the application be approved. The REO is also able to do this if the Lead Reviewer is unable to.

Reviewers in **FST** will be assigned the role of both **reviewer** and **lead reviewer** at the same time as only one member of the **FST REC** will review an individual application.

In **FHM** members of the faculty research ethics committee (FREC) will be assigned as the **Reviewer** for all applications discussed during its monthly committee meetings so that its members can view all applications. In addition, a **Lead Reviewer** will be chosen from the committee to present this application at the FREC meeting.

In **FASS/LUMS** either one or two reviewers will be assigned to an application. Where two reviewers are assigned one will act as the **Lead Reviewer** and the second will act as the **Reviewer**. Where only one member of the committee is assigned to an application they will have the role of both **Reviewer** and **Lead Reviewer**.

- d) The review process: The review process is explained in detail in section 4. All comments must be added inside the REAMS form. After each question, there is the opportunity to add a comment. To do so, press the button "Add comment", then click at the relevant question and add the comment. With regard to uploaded documents, we recommend that you write your comments on the REAMS application at the position of the upload of that file. This is important because all comments made within the REAMS form are collected there will be summaries of comments, counts of comments, etc. and those would miss any comments placed with "Sticky notes/comments" onto the uploaded documents and sent back in the correspondence. When you finish the reviewing press "Close Comments" and the form will lock, that means you cannot access it any more. To unlock an application please contact your REO.
- e) Finishing your review: When the reviewers have finished their comments, they click "Send Comments to Lead". The lead reviewer will receive an E-mail with a table summarizing who has sent the reviews/comments (Section 4.6). If the lead reviewers would like to check the status of the application at any time before that, they can look at the timeline overview. Once they have performed their own review or compared the comments, the lead reviewers have multiple options:
  - a) the application needs another review,
  - b) return to reviewers for more clarification,
  - c) return to applicant,
  - d) send it to the REO to add it to a meeting,
  - e) send to chair.
- f) Changes by the applicant: The applicant will receive an E-mail with the list of comments and a link to the application form. After they have incorporated these changes and uploaded new revised documents, the review process goes into the second round. The reviewer(s) will be directly shown the changes in an overview window and led to the changes in the application.

- g) Approve application: Depending on the faculty procedure, the chair or lead reviewer can press the "approve" button and an approval E-mail to the applicant will be generated.
- h) **Create meeting:** The Research Ethics Officer (REO) is responsible for creating meetings, inviting committee members and adding applications to the meeting. You can E-mail the REO (or send them a communication within REAMS) if you think that the application should be reviewed in a meeting.

#### 2.2 Two different workspaces: "outside the form" and "inside the form"

In order to work as reviewer in REAMS one needs to appreciate the differences between working **on** the application form and working **inside** the application form.

#### 2.2.1 Working outside the application form:

This means working on the elements an application that does not include the actual content of the application form. This includes procedures like closing the review comments by locking the form, sending the form to the REO, looking at the timeline of the application, sending mail to the applicant "Return to Applicant". The overview screen for working on the form is the **timeline overview (see section 3.2)**.

#### 2.2.2 Working inside the application form:

Reviewers work mostly in the application form. This is when you read the application as if you would read a word or pdf file. However, the application is broken into different sections within REAMs and those sections are summarized in the **navigation overview** (see section 3.3). The navigation overview helps you navigate to specific sections of the application.

## 3. Overview pages

#### 3.1 Work Area

When you sign in as reviewer you will be greeted with the **Work Area** screen (for applicants in the Forms part of REAMS this page is called **home screen**) and you will be shown the applications that **you need to review** (shown in Figure 1). Only the REO sees all the applications present in the REAMS system and the Chairs see all the applications for their FREC.

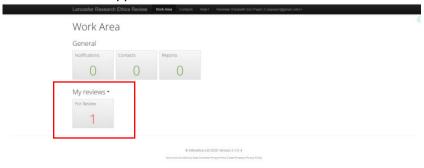


Figure 1- Work area

Click on the "For Review" button (shown in the red box in Figure 1) and you will see a list of all the applications for review that have been assigned to you.

A green star in the row "User Reviewer Type" (shown in the red box  $(\underline{1})$  in Figure 2) indicates that you are the lead reviewer of this application. All reviewers assigned to the respective application are

listed in the final column (shown in the green box (2) in Figure 2). With one click into the yellow field the application form will open, and you will be led to the timeline overview page of this application.



Figure 2- For review

#### 3.2 Timeline overview

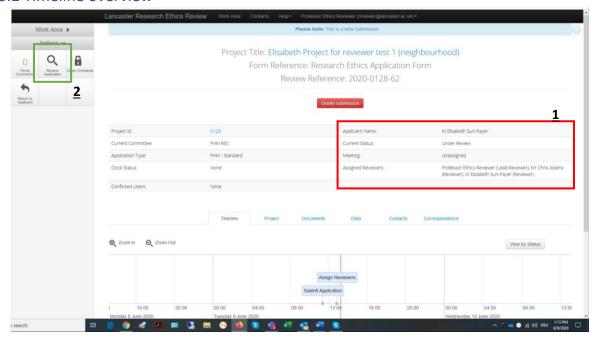


Figure 3- Timeline overview

The timeline overview page provides information regarding what has happened to an application so far. In the example shown in Figure 3, three reviewers were assigned after the application was submitted (Shown in the red box (1) in Figure 3).

So far, you were working "on the application" (see section 2.2). You can open the application for the review by clicking on the button "Review Application" in the Actions box (shown by the Green box (2) in Figure 3) and you will enter into the application (see section 2.3).

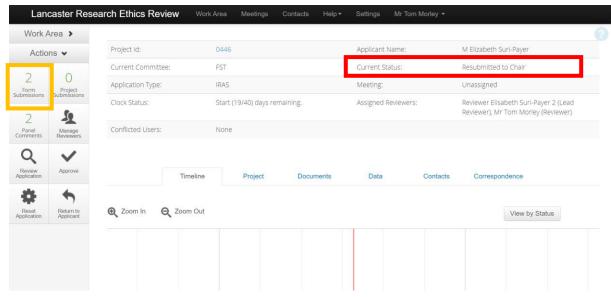


Figure 4

The application timeline allows you to see the past stages of an application. You may need to zoom in or out to see all the information using the scroll on your mouse. Please note: If the application has been resubmitted by the applicant there will be a separate timeline for every version of the application submitted. To ensure you are looking at the latest version of the application timeline check the "Form Submissions" count under the actions box (orange box in figure 4). If it says "2" or "3" then you need to click on the button and choose the choose the latest version of the application. You can also check to see if you are looking at the latest version of the application form by checking the current status (shown in the red box in figure 4). Old versions of the application will have "Superseded" as their status.

#### 3.3 Navigation overview page

The navigation overview page represents one level "lower" than the timeline overview and depicts the different sections of the application, similar to a table of contents. This structuring helps to navigate faster through an application, as you can select directly the sections of interest. These sections are also the units in which the comments and changes are added (see also Section 4.3). You can access this page by clicking the "Review Application" button shown in the green box in Figure 3.

All the fields with blue text can be clicked and will lead you to their respective part of the application (you can also identify these fields by hovering your mouse over them to see if the text contains a hyperlink). An Asterix (\*) next to the row titled "REC Review Required" means that files (e.g. participant information sheet (PIS), consent form etc.) have been uploaded to this part of the application (see also Section 4.6). Once you are inside an application reviewing it, you can always come back to this navigation overview by pressing the "Navigate" button in the Actions box (shown by the blue box (1) in Figure 6).

You can also view all the documents associated with the application in one place (such as the PIS, Consent forms, Debriefing sheets, etc.) by clicking the "Documents" button (shown by the red box (2) in Figure 5).

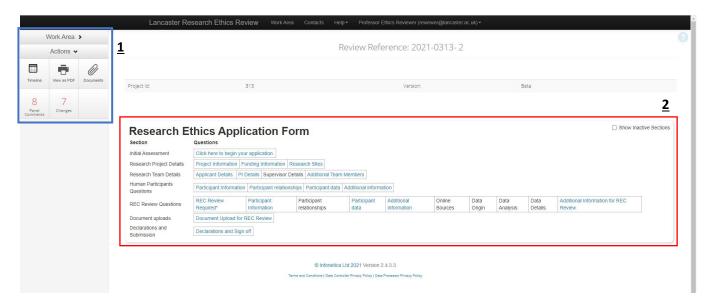


Figure 5- Navigation overview page

#### 3.4 Inside the application (in the application form)

Once you click on one of the blue fields in the boxes under the title 'Research Ethics Application Form' (shown in the red box (1) in Figure 4) you will get inside the application. The first part of the application is called the 'Initial assessment', and it lays the groundwork to what kind of application this is (e.g. human participants, human data, IRAS application etc.). This section determines the follow up questions the system asks the applicant. The second and third part relates to the research team and other basic project details such as research sites and funding. This is followed by a series of questions about the research participants or data that the system uses to decide if an application is a low-risk project that will pass self-review. Only those applications that show a higher risk level will proceed to REC-review and thus be presented to the reviewer. Thus, the "real review" starts at the section "REC review questions".

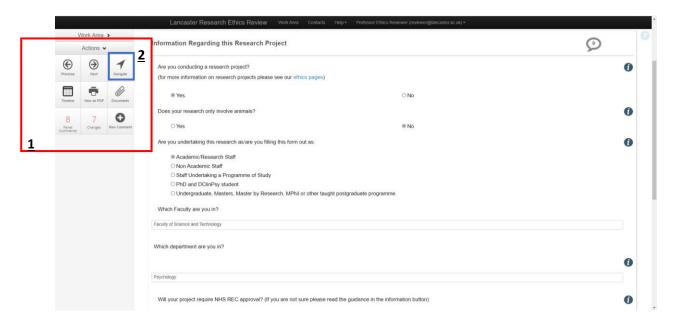


Figure 6- Inside the application form: Initial Assessment questions

#### 3.5 Actions Box

The Actions box (shown in the red box (1) in Figure 6 and the blue box in Figure 5) contains buttons with different functions. The content of the Actions box changes depending on which view/overview you are in and what role you perform. If you are looking for a specific function and you do not see it, change the "level" (for example, navigate from working in the form (Figure 6) to the overviews outside the form (Figure 5)) you are working in. More information on the functions of the buttons in the action box is provided in section 4.3 (outside the form) and section 4.4 (inside the form).

## 4. Review an Application

#### 4.1 Start by signing into REAMS with your name and password.

When you sign into REAMS you will start with the "Work Area" screen (shown in Figure 7 (see also Section 3.1)). The applications you are requested to review are indicated on the "For Review" button (red box (1) in Figure 7), click on this and you will be led to the list of your reviews in the "For Review" section.

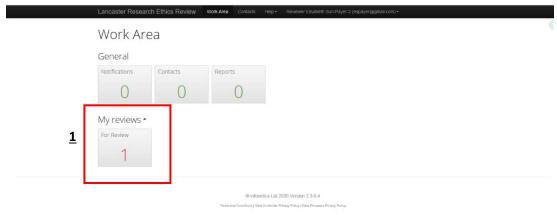


Figure 7 - Work area

Within the 'For Review' section the applications you are requested to review are shown in a series of rows. Click on the row of the application you wish to review, this will open the application on the navigation overview page (Section 3.1). You can also access the applications you are requested to review via 'invitation' (Section 4.2).

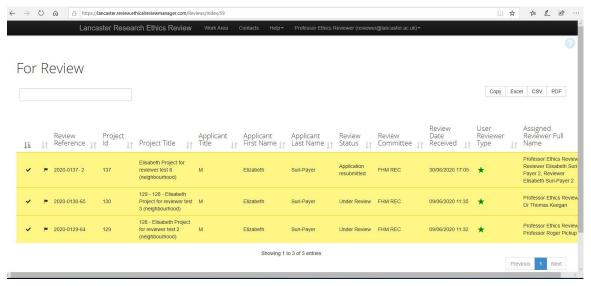


Figure 8- For review

#### 4.2 Start through invitation to review

You can also access an application to review via 'invitation'. Once the REO has assigned an application for you to review, you will receive an E-Mail from Infonetica:

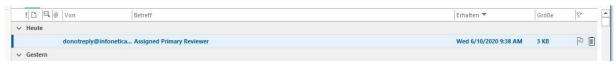


Figure 9- Email from Infonetica.

By opening the mail, you will be provided with a link allowing you to directly open the REAMS application (as shown in Figure 10):



Figure 10- Link to open the REAMS ethics application to review.

#### 4.3 Navigation overview and Actions box

After clicking "Review Application" the navigation overview appears. The buttons in the Actions box (Shown in the red box (1) in figure 11) allows you to a) go back to the timeline overview ("Timeline"), b) print the form if you prefer to have a single pdf or a paper printout ("Print", see Section 6.3) or c) directly refer to a list of documents attached to this application ("Documents"). Further, the number of comments and changes to the form are shown.

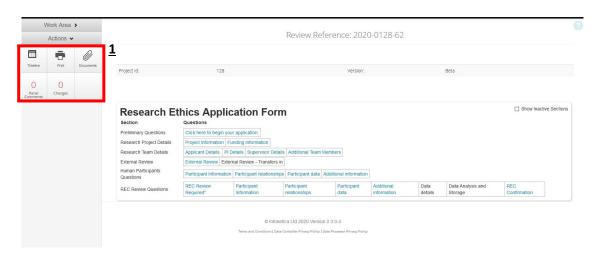


Figure 11- Application navigation overview and Actions box

#### 4.4 Start reviewing (work inside the application form)

To begin to review an application, select the 'click here to begin your application' button (shown by the red arrow in figure 12) in the navigation overview page. Applications are split in the different sections shown in the text boxes under the heading 'Research Ethics Application Form'. You can navigate directly to a section of the application by selecting one of the boxes with blue text.

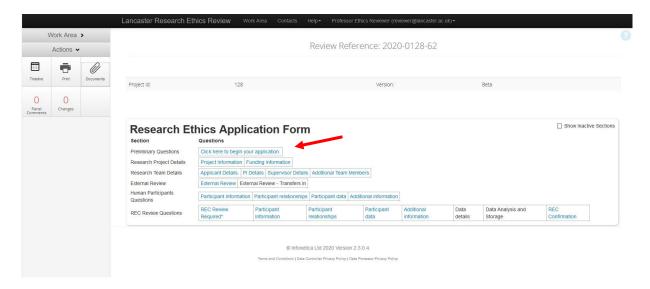


Figure 12- Begin your review of an application

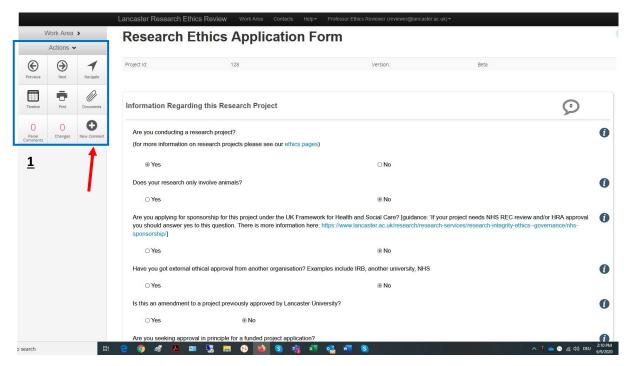


Figure 13- Reviewing an application and Actions box

Once you get inside the application you will also recognize that the button in the Actions box have changed (Shown by the blue box  $(\underline{1})$  in figure 13). The Actions that can be performed during review are: a) go back a page ("Previous"), b) go forward a page ("Next"), c) go to the navigation overview ("Navigate"), d) go to the timeline overview ("Timeline"), e) print ("Print"), f) look at the attached documents ("Documents") and g) add new comments ("New Comment"). The Actions box also shows how many comments have been added, and how many edits have been implemented by the applicant.

To review an application read and scroll down each page. After each section, you will be asked to use the "Next" arrow in the Actions box to get to the next section. The sections used in the application depend on the answers the applicant has provided, meaning that reviewers only read the parts that are relevant in the respective application. See section 4.5 for information on how to add comments to an application.

#### 4.5 Add comments

While reading through the form, comments can be added by pressing the "**New Comments**" button in the Actions box (shown by the red arrow in figure 13). The program will then highlight the area of the page you are currently reading and ask which question you want to comment on (shown in figure 14).

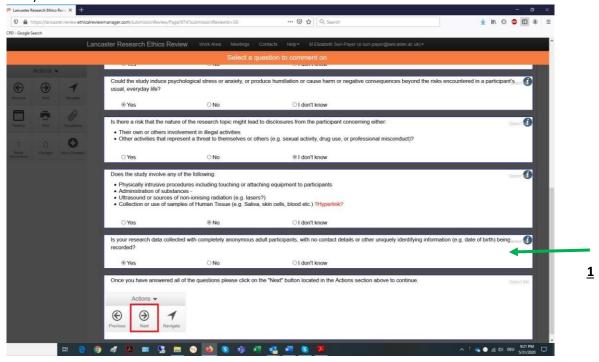


Figure 14- Add reviewer comments to an application

When you click in the field of the relevant question (for example, the question shown by the green arrow in figure 14 (1)) your comment will be inserted exactly at that question. Then you add your comments into the "Add Comment" window:

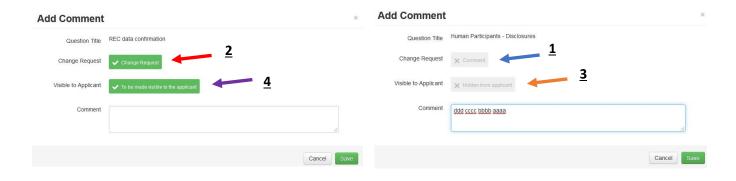


Figure 15 - Add Comment window

At the top of the "Add Comment" window REAMS confirms which question you are commenting on by showing the **Question Title**.

Next, the system asks **Change Request**: If this box is grey (shown by the blue arrow ( $\underline{1}$ ) in figure 15), it means that your "comment" is just a comment, but may not need an answer or change by the applicant. To request a correction to the application you must click the grey field. Once you have clicked this field the box will become green and state "Change Request" (shown by the red arrow (2) in figure 15). This also ensures that the changes the applicant makes are recorded in the system,

which will allow you to easily see these changes upon re-review. This is another good reason for making your comments in the REAMS application form rather than solely on the uploaded supporting documents (e.g. PIS, consent form, etc.).

Next, you determine if your comment shall be **visible to the applicant**. For instance, it is possible to add comments visible only to the chair or the research ethics officer, etc. and "hidden from applicant" by leaving this field grey (shown by the orange arrow (<u>3</u>) in figure 15). By clicking into the grey box, it changes to "become visible to applicant" and turns green (as shown in figure 15 by the purple arrow (<u>4</u>)). This means that the applicant will be able to see your comments.

#### 4.6 Read and comment on uploaded documents

As mentioned before a "\*" in the application sections shown in the navigation overview indicates positions where documents have been uploaded (see the red arrow in figure 16).



Figure 16- Read and comment on uploaded documents

When you click on a section heading of the application with blue text (shown in figure 15), REAMS will "jump" to this section. You can also reach those uploaded documents by working page by page through the application form or by pressing the "Documents" button in the Actions box (shown by the red arrow (1) in figure 17).

Figure 17 shows the **REC Review Details** page with the uploaded documents.

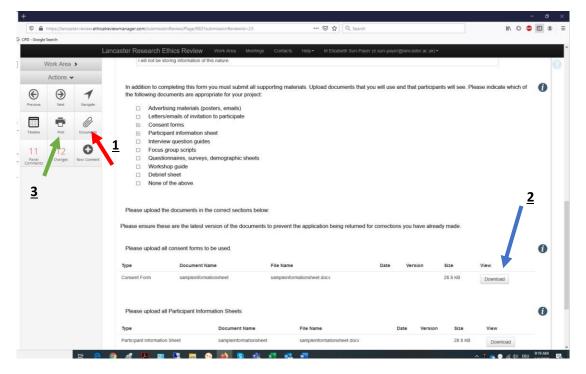


Figure 17- Rec review details with uploaded documents

To view documents uploaded by the applicant (such as the PIS, Consent Form etc.) either click the "Download" button displayed next to the document information (Blue arrow ( $\underline{2}$ ) in figure 17), or click

the "**Documents**" button in the action box (red arrow  $(\underline{1})$ ). This will open the Documents overview page (figure 18).

The documents overview page allows you to download the application documents you select. Be careful to check that you are reviewing the latest version of each document by looking at the version column and date. Another way of collating the application and documents is via the "Print" Button in the Actions box (shown by the green arrow (3) in figure 17). In this context "Print" means collating the sections of the REAMS form and the attached documents into one file (like a pdf); this file can then be either displayed on the computer or downloaded and printed on paper (see Section 6.3).

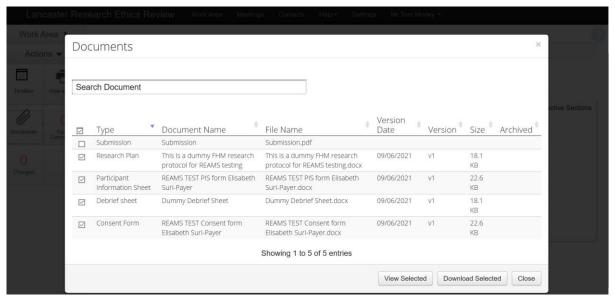


Figure 18- Documents download overview

Comments for these documents are best made in the respective section in the application form. For example, use the "Navigate" button, and then click on Participant Information and add the comments in that section (see section 4.5).

If you prefer to add comments directly on the pdf file, you nevertheless need to alert the applicant using the "Add Comment" window in the REAMS form (see section 4.5).



Figure 19- Add a comment alerting the applicant that you have commented on a file they have uploaded.

You can add notes onto the uploaded pdfs in the form of sticky notes, or as comments if the document is a word file. We recommend that you do this only when absolutely necessary and refer to these in the comments within the application form. Once you have saved your pdf/word file under a new name (e.g. FST.... Review 1), you can add it to REAMS under correspondence in the timeline overview, where you click "+correspondence" (see the red arrows in figure 20).

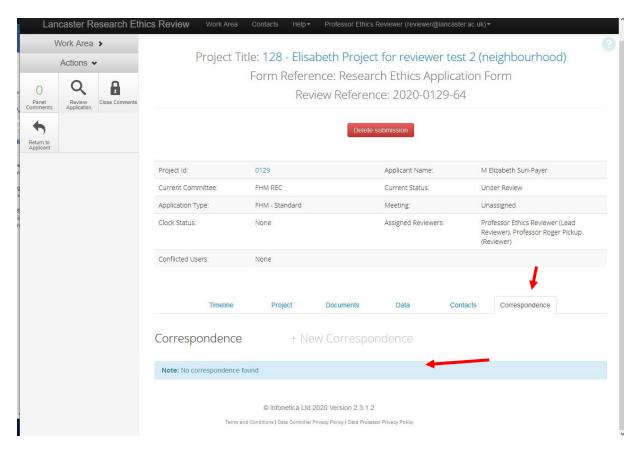


Figure 20- Add correspondence

The correspondence window will open (figure 21). Alert the applicant to the changes by describing them in the text box, add your file using the Browse function and then press "send". Using correspondence function you can send any comment you wish to the applicant and as well as send other files, e.g. institute guidelines or additional forms to the applicant.

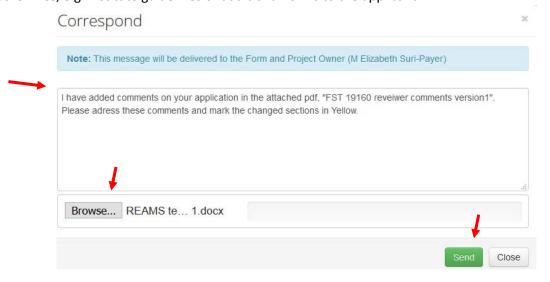


Figure 21- Correspondence window

The applicant will receive an "in REAMS" notification (not an E-mail) which they will only see within REAMS. Clicking on the notification will lead them to the correspondence and the downloaded document.

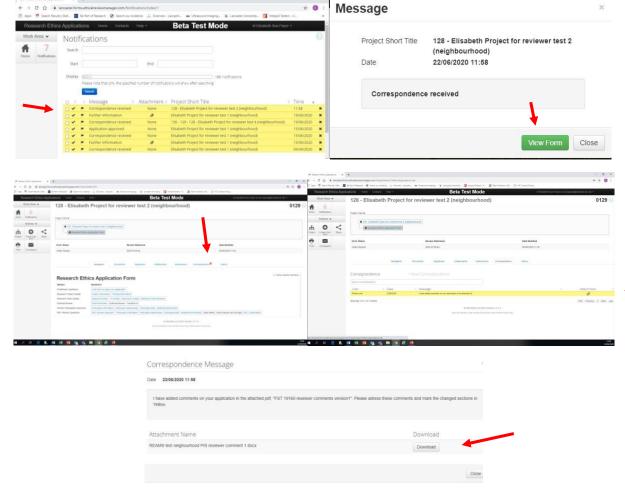


Figure 22- An example of how the applicant will be notified of new correspondence from their reviewer

Applicants will receive a general statement in the E-mail they receive from REAMS telling them the lead reviewer has assessed their application, to ensure that they read this additional correspondence. This whole procedure is a little cumbersome, and is not the recommended method of providing feedback unless absolutely necessary. All comments added to documents MUST ALSO be added/referred to within the REAMS form (as explained in Section 4.4) to be captured in REAMS. Failure to do so may be problematic when you review the revised application (see section 5.3). Therefore, remember that all work on the application should be "inside the form", correspondence such as this (i.e. sticky notes added to a pdf of the PIS) is outside the form and therefore outside the routine workflow.

#### 4.7 Finishing your review – Sending Comments to the Lead Reviewer

Please note that this section **does not apply** for reviewers in **FST** as applications submitted to this faculties will only ever have one reviewer. As a result, reviewers from FST are always classed as the **'Lead Reviewer'** in REAMS (please skip this section and see section 4.8).

Applications submitted to **FASS-LUMS** may also sometimes only have one reviewer. Here the single reviewer will be classed as the 'Lead reviewer'. Applications submitted to FASS-LUMS requiring two reviewers will have a 'Reviewer' in addition to a 'Lead Reviewer'. If you are in reviewing an application submitted to the FASS-LUMS REC you will be informed if your role is that of the 'Lead Reviewer' or 'Reviewer'.

Members of the **FHM REC** committee will be assigned as a **'Reviewer'** for every application discussed at the monthly FREC meeting so that they can view all applications. In addition, a **'Lead Reviewer'** 

will be assigned to each application to conduct a detailed review and then present the application at the FREC meeting.

In order to declare that you have finished your review as a 'Reviewer', navigate into the timeline overview (shown by the green box (1) in figure 23).

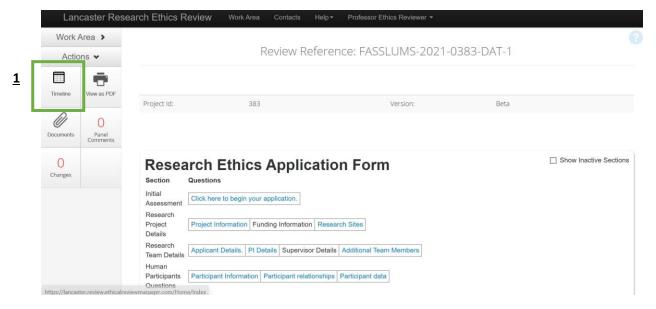


Figure 23 - Navigate to timeline overview

Then click the "Send Comment to Lead" button in the Actions box (shown by the red arrow in figure 24). This Will send your comments to the 'Lead Reviewer' of the application.

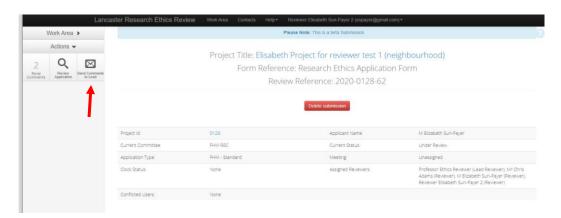


Figure 24- Send comments to lead

You will be presented with the "Send Comment to Lead" window where you can add a message for the lead reviewer, if you wish so (figure 25). The Lead Reviewer will then receive an E-Mail that you have finished your review.



Figure 25- Send comment to lead reviewer window

Sending comments to the Lead Reviewer does not prevent a Reviewer from adding more comments later. Comments can be added from all reviewers, REOs and FREC Chairs until the Lead Reviewer performs "Close Comments" (see below). The Lead Reviewer of an application can choose if they would like the applicant to see individual comments from the Reviewer/Reviewers or not.

#### 4.8 Close Comments by Lead Reviewer:

If you are reviewing an application submitted to the FST FRECS you will be classed as the applications 'Lead Reviewer'. If you are reviewing an application submitted to the FASS- LUMS REC or FHM REC you will be informed if you have been assigned the role of 'Lead Reviewer' or 'Reviewer'. If you are the only reviewer of an application submitted to FASS-LUMS FREC you will automatically be assigned the role of 'Lead Reviewer'. Every time a 'Reviewer' closes their comments, the 'Lead Reviewer' in FASS-LUMS or FHM will receive the notification E-mail shown in figure 26. This notification lists how many reviewers have already sent their comments and when. Your FREC Chair/Deputy Chair and REO can also add comments to an application (for example, comments raised by members of the FHM REC during the FHM REC meeting can be added by the REO after the meeting).

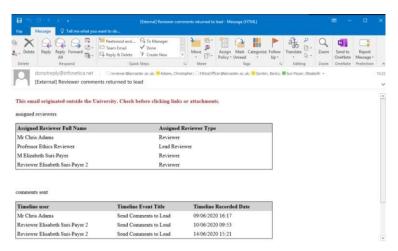


Figure 26- Reviewer comments notification

Once you have completed your review as the Lead Reviewer, navigate to the Timeline overview page of the application and press "Close Comments" (shown by the red arrow ( $\underline{\mathbf{1}}$ ) in figure 27).

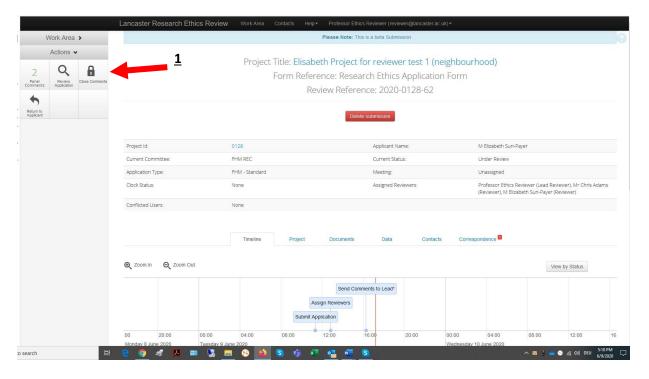


Figure 27- Lead reviewer returning the review to the applicant

You also have the option of adding some additional comments when closing the review as the Lead Reviewer (figure 28).



Figure 28- The lead reviewer can add some additional comments before returning the review to the applicant

#### 5. Comments closed – what next:

#### 5.1 Options for the Lead Reviewer

Once you have closed the comments the timeline overview page will shows the status "Comments Closed" (Red box ( $\underline{\mathbf{1}}$ ) in figure 29) and a new set of buttons will appear in the Actions box (Green box ( $\underline{\mathbf{2}}$ ) in figure 29).

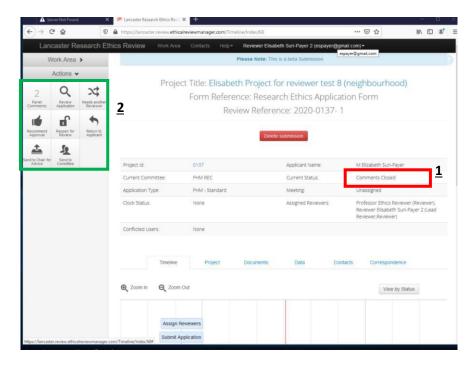


Figure 29- Comments closed

The new buttons in the Actions box allow the lead reviewers the following choices:

1) "Panel Comments": This allows Lead Reviewers to view and compare Reviewer comments. Clicking this button opens the 'Panel Comments" window showing an overview of these comments (figure 30, see also Section 6.2). The lead reviewer can use this feature to see if multiple reviewers had the same concern. Using the edit function, the Lead Reviewer can also choose to make comments invisible or visible to the applicant.

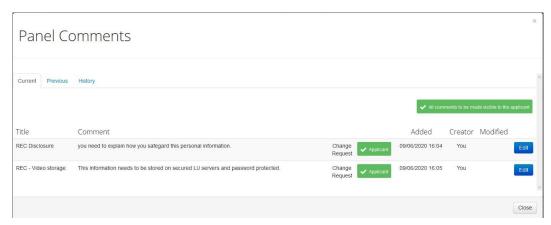


Figure 30- Panel comments overview

- 2) "Review Application": This button allows the Lead Reviewer to review the application.
- 3) "Needs another Reviewer": The Lead Reviewer can ask for another reviewer to assess an application. Clicking this button will open the "needs another reviewer" window (figure 30), please add an explanation for the request in the 'Timeline Notes' text field. The applications current status on the timeline will change to "Recommend for Further Review" (shown by the red box (1) figure 32), thereby alerting the REO to add an additional reviewer.



Figure 31- Needs another reviewer

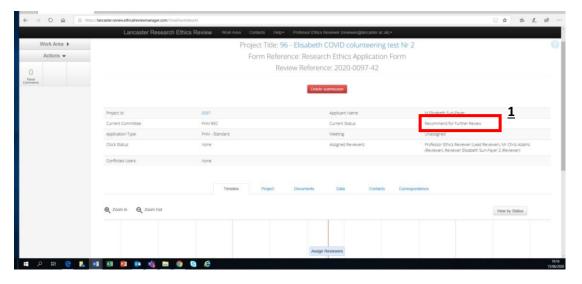
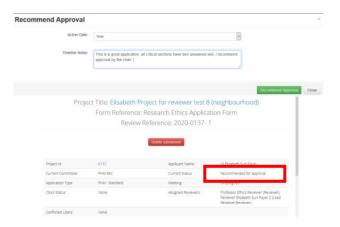


Figure 32- Recommended for further review

4) "Recommend Approval": If you are satisfied with the application as the Lead Reviewer no further comments for the applicant to address you can send the application to the chair for approval using this button (some Lead Reviewers may also have the authority to approve the application themselves depending on the FREC rules, you will be informed of this before you begin to review an application).



"Reopen for review": As the Lead Reviewer you can also open the review process again and send it back to the 'Reviewer/s' to amend or add additional comments. This is only applicable for Lead Reviewers in FASS-LUMS who are not acting as the sole reviewer of an application.



Figure 33 Reopen for review

By doing so, the timeline of the application will change back to "Under Review" and thus the buttons in the Actions box change again (figure 34).

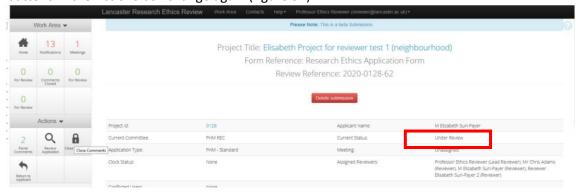


Figure 34 Under review

- 6) "Return to applicant": Use this function to send the application back to the applicant with your comments (see Section 5.2).
- "Send to Chair for Advice": Use this function to send the application to the FREC Chair if you have any questions.



- 8) **"Send to REO for Advice":** Use this function to send questions or queries to your Faculty Research Ethics Officer.
- "Send to Committee". Send to committee actually means that the REO will receive notice that this application should be added to a committee meeting for discussions. The REO can discuss this with the Chair before adding it to an upcoming meeting.

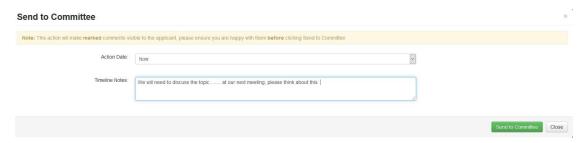


Figure 35 Send to committee

#### 5.2 Return to Applicant

The **Lead Reviewer** can send applications back to the applicant at any stage, however, in most cases the Lead Reviewer will send the application back to the applicant only after they have completed their review and comments are closed. This can be achieved by pressing the "**Return to Applicant**" button in the Actions box (Green box (<u>2</u>) in figure 29). The "Return to applicant" window for the creation of an E-mail will then open (figure 36). All comments will be added into a single list, irrespective of who created the comments (reviewers, research ethics officers and chairs can add comments for example). We recommend that you use the predetermined text to the applicant, but this can be overwritten and your own version used instead if needed using "Existing" and "My draft" buttons.

Action date: Don't change this, just leave it on "Now".

**Timeline note**: This is for internal information within the committee. The field can stay empty.

Return to Applicant			)
Note: This action will make marked conne	its visible to the applicant, phone crown you are happy with their before	ciscong Return to Approximit	
Action (	MMC Now	8	
Timeline N	Mrs.		
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click here to see you application: https://lank Kind regards	esterforms, ethicalrevia emanages con Project Ondex [13]		
Professor Ethics Reviewer on behalf of chair			
Easing by Duby Preview		Setum to Appe and	Close

Figure 36 Return to applicant

Pressing "Preview" (red arrow in figure 36) opens a preview of the E-mail. Once you are happy press the green 'Return to applicant' button in the bottom right corner of the window.

The applicant will then receive an E-mail from Infonetica containing a list of the reviewer comments and a link leading them directly to their application.

Once the applicant opens the link and clicks on the button "Reviewer comments" in the Actions box, these comments will appear in a new window (as seen in figure 37).



Figure 37 Overall reviewer comments

#### 5.3 Applications back for Re-review - Changes

Once the applicant has resubmitted their application the Lead Reviewer/Reviewer will receive an E-Mail to notify them. The notifications section in the Work area in REAMS will notify them that there is an application to review. The re-submitted applications timeline overview will state "Application resubmitted" next to its current status (red box in figure 38).

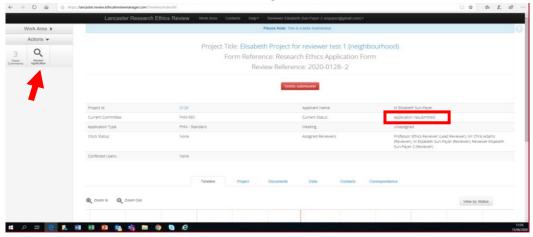


Figure 37 - Application for re-review

Clicking on the "Review Application" button (red arrow figure 38) will open the application at the navigation overview page (figure 39).

Here you can either click on the "Changes" button (shown by the red arrow in figure 39) to open the "Changes" window to be directed directly to the applicants revisions or "click here to start application" and scroll through the form until you reach the amended sections.

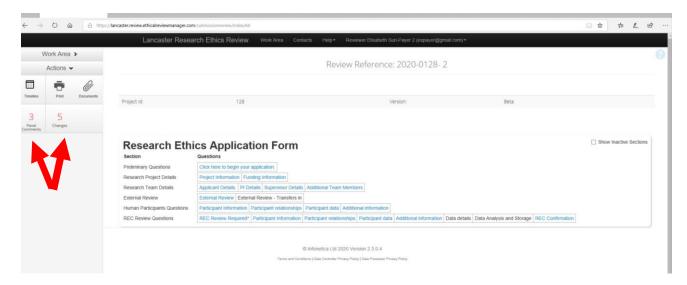


Figure 38 Navigation overview



Figure 39 Changes window

The changes window (figure 40) alerts Lead Reviewers/Reviewers to which sections of the application changes have been made to. In the example above five "Changes" are shown but only three "Panel Comments" had been made (the reviewer is notified of the number of changes and panel comments in the Actions box in the application navigation overview page (Red arrows, figure 38)). Please note that it is possible that the number of Changes made to an application may not equal the number of Panel Comments. For example, there may be reviewer comments without change requests associated with them (as explained in Section 4.4) or an applicant may have introduced a change themselves that had not been asked for. Thus, the numbers of Panel Comments and Changes do not always correlate.

Clicking on the text in the changes window (figure 39) will lead reviewers directly to the appropriate section in the application form. The question within this section where the applicant introduced a change is marked with a blue frame and shows the new corrected text (shown by the red arrow in figure 40). At the top of this section is a light blue banner saying "Note: The applicant has changed an answer within this panel since the last submission" with a dark blue "View Changes" button.

Reviewers can see these changes by clicking the "View Changes" button (shown by the red box  $(\underline{1})$  in figure 40).

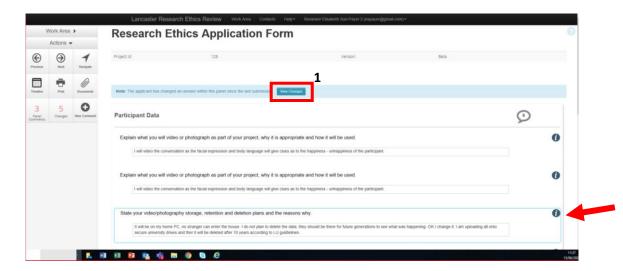


Figure 40 Change introduced by applicant in the form

After clicking "View Changes" REAMS will display new text additions highlighted in green, whilst deleted text is shown in red with a strike through (as seen in figure 42)



Figure 41 View changes

When reviewing new documents uploaded by the applicant, reviewers should please keep in mind that there may be multiple versions of a document uploaded to REAMS. For instance, in figure 42, there are now two PIS forms, including a "V2" with the corrections (shown in the blue box  $(\underline{\mathbf{1}})$ ). Applicants are instructed to "delete" old files when uploading new versions, however please be aware of the possibility of multiple or old version of supporting documents being displayed. If there have been multiple rounds of changes, the system differentiates between current changes, previous changes and historic changes (see section 5.4).

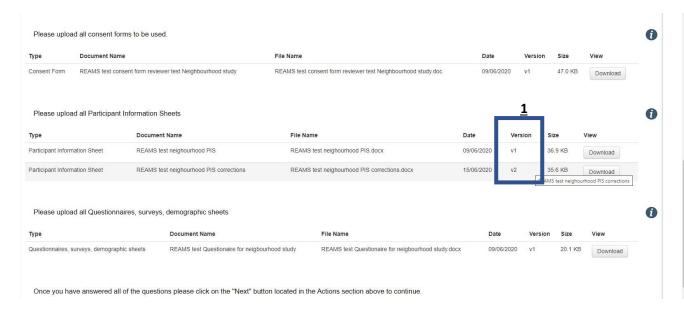
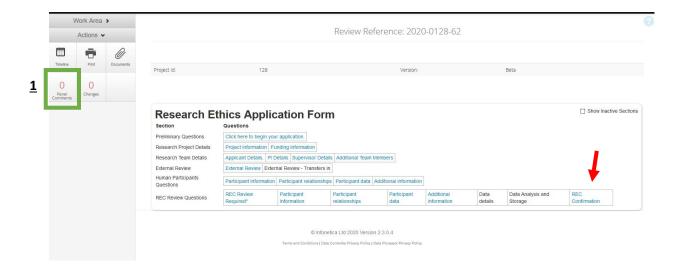


Figure 42 Documents uploaded by the applicant

## 5.4 Comments from the previous round of review



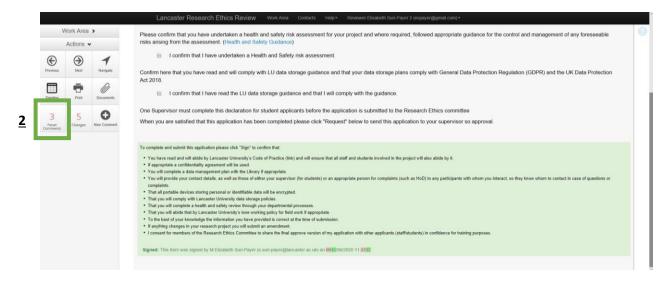


Figure 43 REC Confirmation

If you click "Panel Comments" button in the actions box (Green boxes ( $\underline{1}$  and  $\underline{2}$ ) in figure 43) when reviewing an application that has been resubmitted by an applicant, you will notice that there are no comments in the 'Current' tab in the Panel Comments window. As this is a new round of review there are no comments from this round yet. Click the 'Previous' tab to see the comments from the previous round/s of reviewing (Red arrow in figure 44).

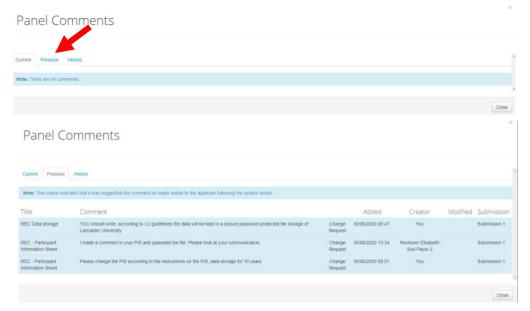


Figure 44- Panel comments

#### 5.5 Approval of Application

Some Lead Reviewers will have to ability to approve an application on behalf of their FREC. To approve an application as an approver Lead Reviewer, click the 'Close comments' button in the actions box (Red arrow figure 45). Then click the 'Approve' button in the actions box. An E-mail will be automatically sent to the applicant. You can see the status of the application by checking the 'Current Status' column on the navigation overview page (shown in the red boxes ( $\underline{\mathbf{1}}$ ) in figures 45, 46 and 47).

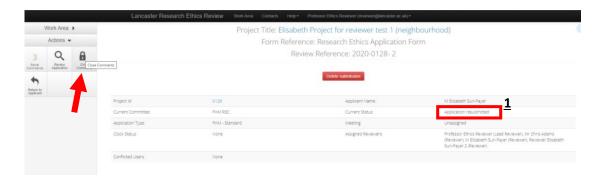


Figure 45- Close comments to approve application

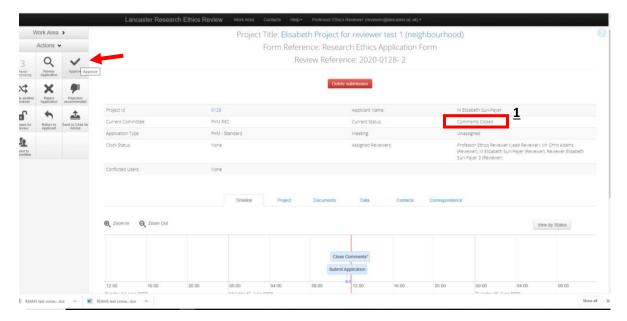


Figure 46- Approve

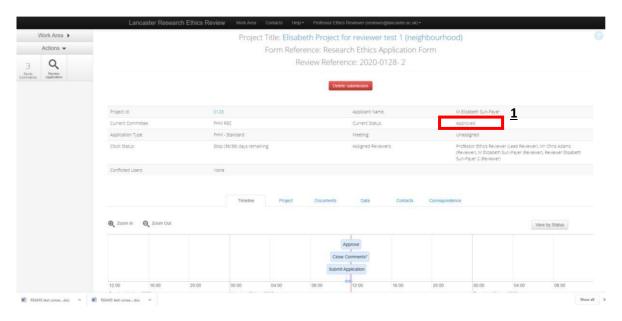


Figure 47- Application approved

If you are a Lead Reviewer without the ability to directly approve an application you will get the button "Send to chair" in the actions box instead (Green box ( $\underline{\mathbf{1}}$ ) Figure 49). Clicking this button will send the application to the chair for their final approval.

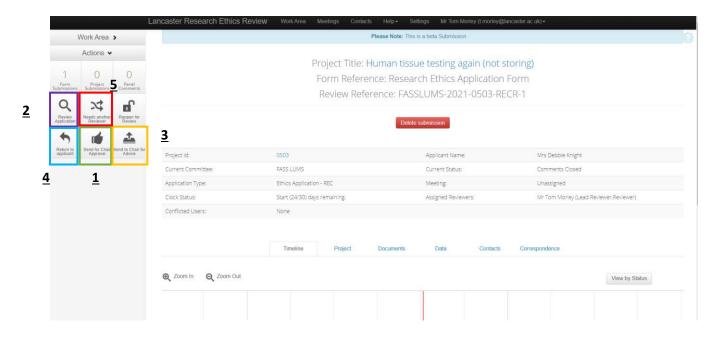


Figure 48- Recommend for approval

If you are not sure yet, you can reopen the application for review (Purple box ( $\underline{2}$ ) figure 49) or send to the chair for advice (orange box (3)). Select 'Return to applicant' to return the application back to the applicant if you would like them to make further revisions (blue box (4) figure 49). To request that another reviewer takes a look at the application press the 'Needs another reviewer' button (red box (5)) and explain in the pop-up box why the application needs another reviewer.

Please contact your faculty REO if you are experiencing any problems. The REO can reset an application to an earlier state (e.g. if you have sent an application to the chair by mistake or approved an application by mistake).

Regular Reviewers can send their comments to the Lead Reviewer once they have finished their rereview of the application. This is the same process described in section 4.7.

#### 6. Further Functions

#### 6.1 Notifications

In the example in figure 49, I have signed into REAMS as 'Prof. Ethics Reviewer' and am looking at the 'Work Area' page. I am told that I have 17 notifications, and 1 application "For Review" by the tiles on this page.

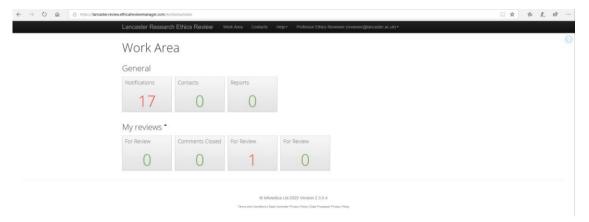


Figure 49- Notifications

After clicking on the Notification tile in your Work Area in REAMS you will receive a list of all of your notifications (Figure 50). You may receive a notification for a variety of reasons, including to inform you that an application was assigned to you, returned to an applicant, assigned to a reviewer or accepted, further messages, alerts to E-mails, instructions, meeting invitations, cancelations, etc.

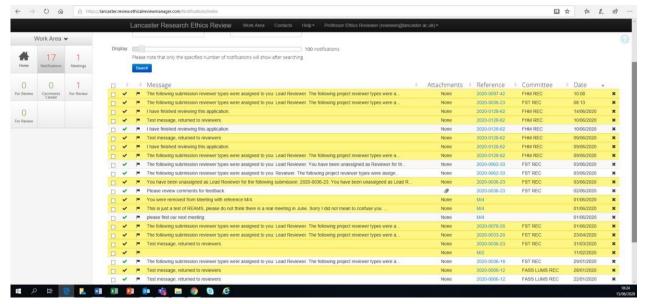


Figure 50- Notifications list

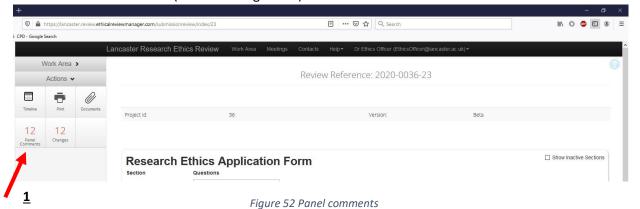
On the left side of each notification row, before the message column text, you can mark the notifications as read/done (green tick mark) or with a red flag (to indicate that you need to respond) (Figure 51). To label/delete multiple notifications (bulk action), click in the little box in the front of the rows and mark all the relevant notifications. To open an application, click on the blue reference number of the application in the 'Reference' column.



Figure 51- Mark notifications

#### 6.2 Panel comments

In the Actions box of the application form and in the timeline overview pages, you will find the button "Panel Comments" (Red arrow Figure 52).



REAMS records all the comments that have been entered into the REAMS form (not on pdf or word documents). This is summarized over multiple rounds of reviews if applicable. When clicking on the

button "Panel comments" the Panel Comments window opens (figure 53).

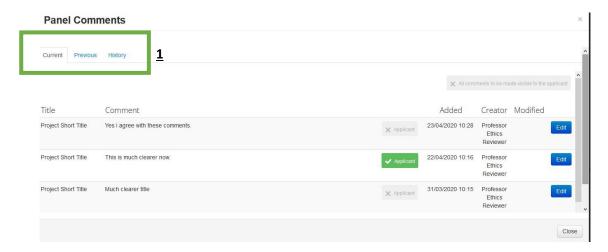


Figure 53- Panel comments window

Comments are divided into **Current** comments (of the ongoing round of review), **Previous** comments (the last round of reviews) and **History.** You can view these by clicking onto the different tabs at the top of the window (Green box (<u>1</u>) figure 54).

#### 6.3 Print

If you would like to print or view a pdf of an application, you can make use of the "Print" button in the Actions box of the navigation overview page (shown by the arrow in figure 54).

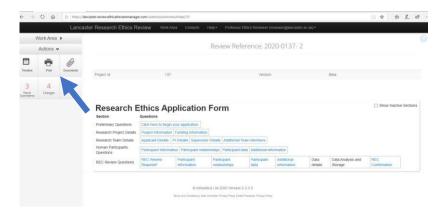


Figure 54 Print application

The "Print Form" will the open:

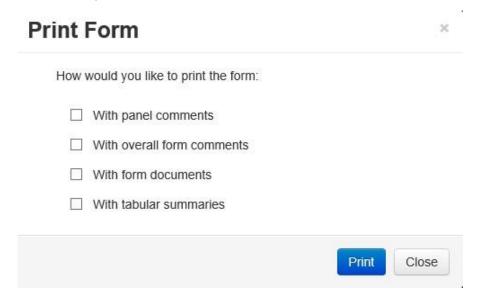


Figure 55- Print form

"Print Form" means that the various sections of the REAMS form will be compiled into a single document (pdf). If you choose to print the REAMS form with the attached supporting documents ("with form documents"), then you will receive one long pdf with the application in front and all the documents at the end. Please note that when reviewing an application that has been converted into a pdf or printed off you cannot see the changes the applicant made; you will only see the newest version of the application. However, at the end of each section you will be able to see the comments that had been added by the reviewer if you have selected "with panel comments" in the print form screen.

#### 6.4 Tips for reviewing applications as a pdf

If you prefer reading the application in one continuous document rather than in the sections in the REAMS form, then create a split screen (or use your two screens) and have the REAMS form on the left side and the pdf file of the application on the other side. You can create a pdf of the whole application under documents using the print function (see section 6.3). Please remember to add your comments in the REAMS form itself at the correct location rather than commenting on this PDF of the application form. In some cases, you may feel the need to add comments to a pdf or word

documents attached to the application in REAMS by the applicant, such as a PIS. Please see section 6.5.

You may like to take a screenshot of the panel comments (as you cannot keep the panel comments window open and at the same time open the changes window) and put it to one side of the screen or on your second screen. Then open the changes window and check the changes the applicant has made inside the REAMS form on the second screen (see Section 5.3).

#### 6.5 Tips for reviewing applications with pdf/word document attachments

Applicants are asked to upload supporting documents such as PIS and consent forms to the REAMS system as Pdfs or Word documents. Whilst we don't recommend commenting directly on pdfs or word documents uploaded by applicants (these comments are not tracked by the system so may be 'lost) you <u>must</u> always add a (short) comment in the REAMS system at the appropriate location. This is needed to enable the Lead Reviewer, Chair and REO to see all comments together and it helps to track the comments and changes. It also helps when you "re-review" an application as the system will lead you to the appropriate location in the application and you do not have to read the full form again (please see section 5.3).

#### 6.6 Screen does not show the Work Area tab or Actions buttons

If you open the screen in a window which is too small then the "Work Area" tab and "Action Buttons" will not be visible (figure 58). Once you widen your window or use the full screen mode in your web browser, they will reappear (figure 59).

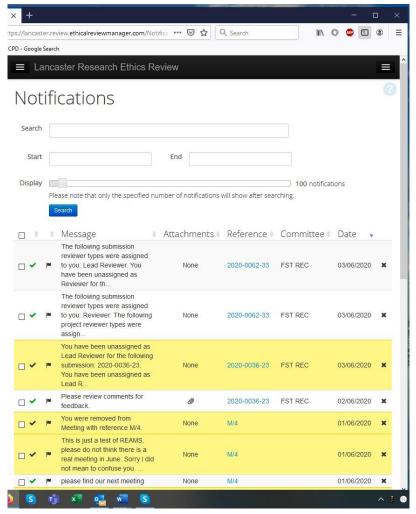


Figure 58- Work area is too small to see actions box

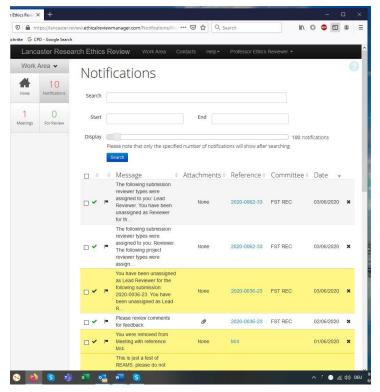


Figure 59- Actions box visible in work area

# 7. Guidance for Committee members (reviewers) when reviewing applications for projects which involve special categories of personal data.

In REAMS, when an applicant answers, 'Yes' to, 'Will you be gathering/working with any special category personal data?' their application will require REC review (e.g. the application will need to be reviewed by reviewer(s) rather than be cleared by 'self-review'). This has been agreed with the Information Governance Officer to meet data protection requirements. The information below is to help reviewers to consider issues when reviewing an application for a project which will use special category data.

To note, special categories of personal data includes 'sensitive personal data' such as racial or ethnic origin, political opinions, religious beliefs, sexual life, physical or mental health conditions and genetic data. Sensitive personal data is often referred to as special category data. Further guidance about classification of data is available on the University's IT webpage: <a href="https://answers.lancaster.ac.uk/display/ISS/Information+classifications">https://answers.lancaster.ac.uk/display/ISS/Information+classifications</a>.

Further guidance can be sought here <a href="https://portal.lancaster.ac.uk/intranet/services/policies-andprocedures/general-data-protection-regulations-gdpr/aboutgdpr/">https://general-data-protection-regulations-gdpr/aboutgdpr/</a> and <a href="https://www.lancaster.ac.uk/research/research-services/research-integrity-ethics-governance/data-protection/gdpr-what-researchers-need-to-know/">https://www.lancaster.ac.uk/research/research-services/research-integrity-ethics-governance/data-protection/gdpr-what-researchers-need-to-know/</a>.

#### Issues for reviewers to consider:

- Is it absolutely necessary to collect and use special category data to achieve the stated aims of the research?
- Is the collection of special category data (and the overall research) in the public interest?
- Can the special category data be collected anonymously in the first instance?
- If not, at what point will it be anonymised (should aim for as soon after collection as possible)?
- Will an identifiable copy of the data be retained after anonymisation? If so, what level of security will be applied to this identifiable data? It should be held at a higher level than the anonymised data, e.g. encryption/password protected, held in a folder/file/system that allows very strict access control tools, etc.
- What is the potential impact on individuals/participants if a data breach of the special category data were to occur? Do the security measures applied to the special category data sufficiently mitigate the risk of special category data being breached?
- Is the PIS sufficiently detailed enough and does it adequately inform participants that their
  special category data will be collected as part of the project (researchers should provide a
  list of special category data that will be collected, not just say special category data will be
  collected, e.g. "This project will involve the collection of special category data about you, this
  will include: ethnicity, disability/health information, sexuality", etc.)
- Does the PIS sufficiently inform participants of the purpose of the collection of special category data (appreciate that in most cases this will already be present in the PIS informing participants what the study is about)?
- We should be wary of any project that collects special category data without informing the
  individual, e.g. collecting special category data from social media platforms. This is not to say
  that we should have a blanket 'ban' on these types of projects but just give additional
  consideration as to whether there is a way to inform participants, whether any additional
  safeguards need to be put in place, e.g. only collecting anonymous data in the first place,
  etc.

## GOOD LUCK WITH YOUR REVIEW!

If you have any questions or require further support please write to REAMS Support  $\underline{ reams support@lancaster.ac.uk}$ 

Best regards, your REAMS Team