

HARP Member Portal User Guide for REC Members

Version 2.0 – March 2020

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Owner – Health Research Authority

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1 Accessing the HARP Member Portal

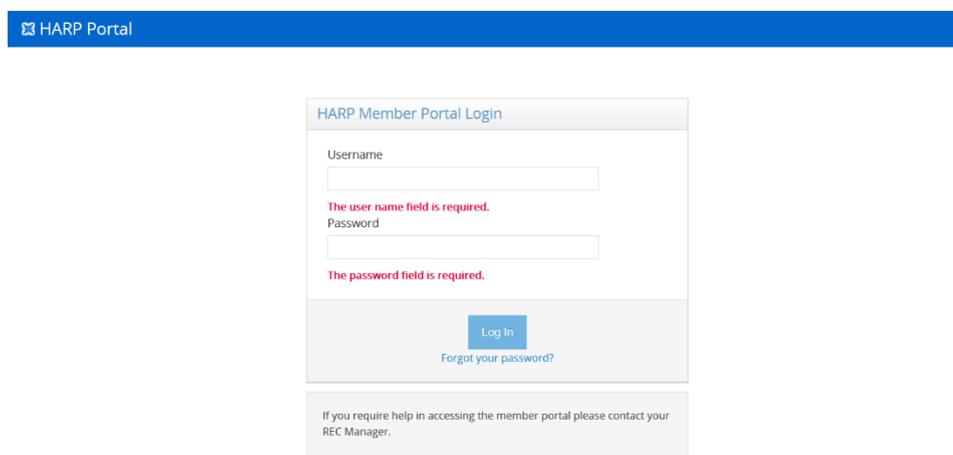
The HARP (HRA Assessment Review Portal) Members’ Portal is a web-based management information system used by the HRA to enable the online electronic review of research ethics applications and amendments.

The Portal can be accessed at: <https://www.harp.org.uk/Portal/Account/Login>

The system is optimised for Internet Explorer (IE) 10 and Firefox; however, it will also work on other web browsers.

To access the Portal, enter your username and password into the relevant fields and click on the Login button. If you do not have a HARP account or have any questions regarding HARP, please contact the member of staff supporting your REC or the HARP helpdesk in the first instance: helpdesk@harp.org.uk

Figure 1 – The HARP Member Portal Login Screen



2 HARP Member Portal Terms & Conditions

On login, you will be presented with the Terms & Conditions of use for the member portal. You will need to tick the box to state that you accept the Terms & Conditions, in order to proceed to use the member portal. If you do not wish to accept the Terms & Conditions or have any questions, please contact your Approvals Officer in the first instance.

Figure 2 – The Terms & Conditions Screen

The screenshot shows the HARP Portal interface. The top navigation bar includes links for Calendar, Meetings, Applications/Amendments, Ethical Review Form, and Help. The user is logged in as Matthew J Rogerson from the London - Hampstead REC. The main content area is titled 'Terms & Conditions' and contains the following text:

By using the portal, I agree to the following conditions:

1. I will not share access, passwords, user names or log on details to the HARP member portal with any other person.
2. I agree that I will hold the information contained in the HARP member portal in confidence, and I will not use the information for any purpose other than in my duties as a REC member.
3. I will only save documents relating to a REC application or amendment on a password protected device.
4. If REC documentation is saved to my device, I agree to delete the documentation relating to the application or amendment after the final opinion has been issued.
5. I agree to inform my REC manager if I become aware that the confidentiality of the documents saved on my device is compromised.

At the bottom of the screen, there are two buttons: 'Accept' and 'Decline'.

3 The User Account Area

To access your account details, select your name at the far right of the Main Menu and then select 'profile'. You are then able to view, edit and save your account details. You can change your password by ticking the Change Password check box and then entering the new password in the fields that appear. You can also view a copy of the Terms and Conditions from here once you have accepted them.

Figure 3 – The User Profile

The screenshot shows the 'My Profile' page for Richard Barrett. The page contains the following fields and options:

- Title: [Empty text box]
- First Name: Richard
- Last Name: Barrett
- Address: [Empty text box]
- Username: richardbarrett@hotmail.com
- Email: richardbarrett@hotmail.com
- Telephone: [Empty text box]
- Fax: [Empty text box]
- Postcode: [Empty text box]
- Committee: South West - Central Bristol Research Ethics Committee
- Country: [Dropdown menu]
- Committee Position: [Empty text box]
- Change Password:
- Old Password: [Empty text box]

4 The Calendar View

The Calendar view appears as soon as you login. It displays every meeting that you are assigned to as a committee member. Using the meeting calendar is the easiest way of accessing meeting documents which have been assigned to you. There are 4 meeting types that can be displayed, and each meeting type is identified by a coloured calendar entry as shown below.

Please note, the calendar view will only show meetings which you have been assigned to attend.

Figure 4 – The Calendar View

Calendar

Legend: Committee (Blue), Sub Committee (Green), Chair's Actions (Orange), PRS Sub Committee (Red)

February 2020

Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
27	28	29	30	31	1	2
3	4	5	6	7	8	9
10	11	12 17:00 Full REC - 12 February 2020 17:00 DO NOT BOOK: CWOW slots only 12 February	13	14	15	16
17	18	19	20	21	22	23

HARP Version 1.2.16 (27440), Build Date 18/12/2019 19:23:14

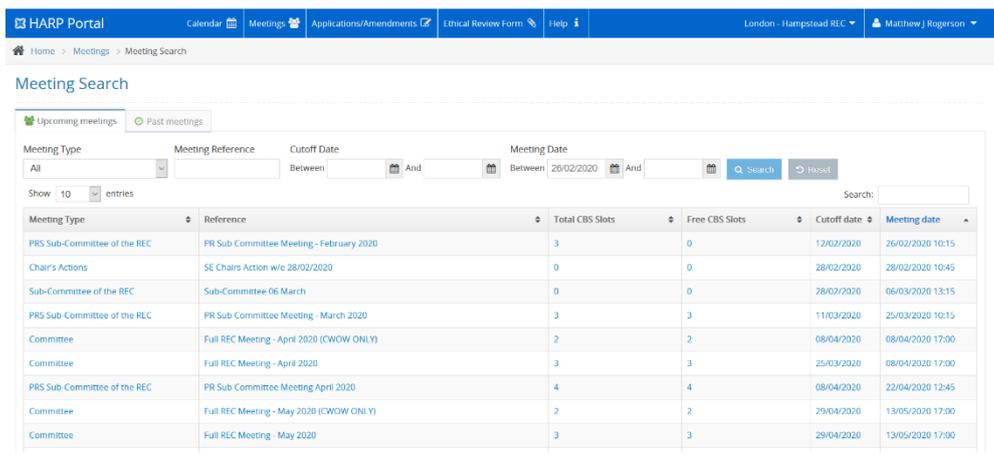
You can view different months by using the arrows in the top right of the screen.

To view a meeting and all of the associated documentation, click on the meeting's calendar entry.

5 The Meeting View

Clicking on the Meetings button in the purple bar at the top of the screen presents you with a list of all the meetings which have been set up for the REC. Clicking on any of the meetings will allow you to view applications or documents which have been added to the meeting.

Figure 5 – The Meeting View

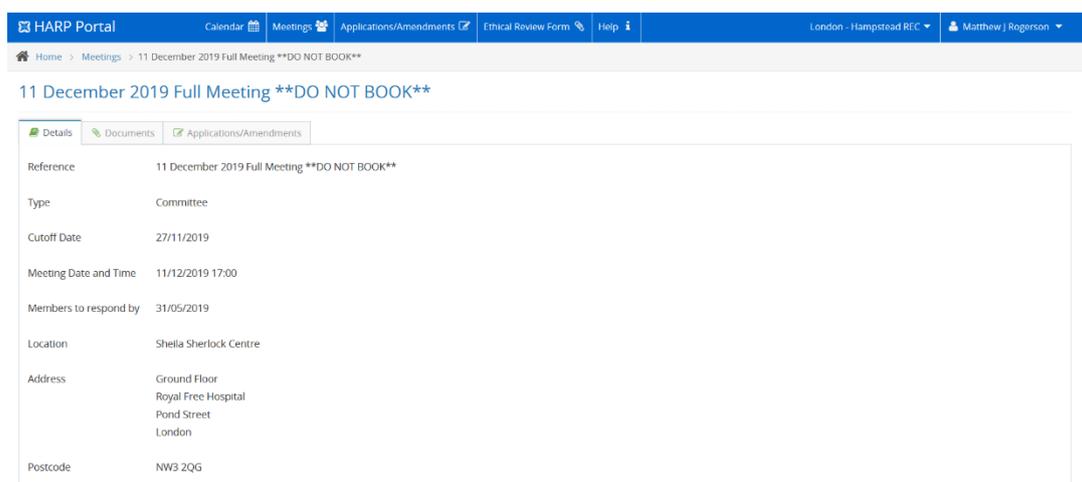


6 Viewing a Meeting

When you have selected a meeting from either the Calendar or Meetings tab you will see the following three tabs associated with the meeting: Details, Documents, and Applications/Amendments.

The Details Tab displays the meeting's details: the meeting reference, the location of the meeting and any notes that have been added by the Approvals Officer.

Figure 6 – The Details Tab



The Documents Tab displays all of the documents (those not associated with an individual application) uploaded against a meeting in HARP and marked as available for review e.g. the Meeting Agenda, Minutes for checking and REC Report. Click on the file name to view and download the document. You can add comments by clicking in the blue comments box.

Figure 7 – The Documents Tab

The screenshot shows the 'Documents' tab in the HARP Portal. The breadcrumb trail is: Home > Meetings > 11 December 2019 Full Meeting **DO NOT BOOK**. The page title is '11 December 2019 Full Meeting **DO NOT BOOK**'. There are three tabs: 'Details', 'Documents', and 'Applications/Amendments'. The 'Documents' tab is active. Below the tabs, there is a 'Meeting Files' section with a 'List' button and a 'Meeting Documents' sub-section. A search bar is present with the text 'Show 10 entries'. A table lists documents with the following columns: File Name, Version, Date Upload, Document Date, Date Sent, and Reviewed. One entry is visible: 'Full Meeting Agenda.rtf' with a 'Comment' button. At the bottom, it says 'Showing 1 to 1 of 1 entries' and has navigation buttons for 'Previous' and 'Next'.

The Applications/Amendments page is where you can access the applications or amendments which have been assigned to the meeting, open the application documents and download them to your device.

To view the details and the documentation associated with one of the applications or amendments, click on either the short title or REC reference number.

Figure 8 – The Applications/Amendments Tab

The screenshot shows the 'Applications/Amendments' tab in the HARP Portal. The breadcrumb trail is: Home > Meetings > 11 December 2019 Full Meeting **DO NOT BOOK**. The page title is '11 December 2019 Full Meeting **DO NOT BOOK**'. There are three tabs: 'Details', 'Documents', and 'Applications/Amendments'. The 'Applications/Amendments' tab is active. Below the tabs, there is a section titled 'Assigned Applications' containing a table with the following data:

Short Title	REC Reference	Application Type
Fabry study with Fabrazyme and Replagal	19/LO/1864	Application (not requiring SSA)
TREATMENT OF PERIODONTAL DISEASE IN SYSTEMIC LUPUS ERYTHEMATOSUS	19/LO/1976	Application (not requiring SSA)
M19-850 - Upadacitinib AD Ph 3 extension study	19/LO/1964	Application (not requiring SSA)
CANnabidiol for Parkinson's Disease Psychosis (CAN-PDP), version 1	19/LO/1967	Application (not requiring SSA)

Below the table, there are two sections: 'Assigned SSAs' and 'Assigned Amendments'. Both sections have a green circle icon and the text 'There are no records found.' At the bottom of the page, there is a footer: 'HARP Version 1.2.16 (27440), Build Date 18/12/2019 19:23:14. © NHS Health Research Authority'.

7 Viewing an Application or Amendment

Clicking on the title or reference number for an application or amendment directs you to the application itself, where you will find the 'References', 'Documents', 'Meetings', and 'Ethical Review Form' tabs as shown in Figures 9 - 13.

The reference tab displays basic details regarding the application, such as the study type, REC Reference and IRAS Project ID.

Figure 9 – The References Tab

The screenshot shows the HARP Portal interface. The top navigation bar includes 'HARP Portal', 'Calendar', 'Meetings', 'Applications/Amendments', 'Ethical Review Form', and 'Help'. The user is logged in as 'Matthew J Rogerson' in the 'London - Hampstead REC' region. The breadcrumb trail is 'Home > applications > Application (not requiring SSA), REC Reference: 19/LO/1864, IRAS Project ID: 266648'. The main heading is 'Fabry study with Fabrazyme and Replagal'. Below this, there are four tabs: 'References' (selected), 'Documents', 'Meetings', and 'Ethical Review Form'. A 'Back to meeting' button is located in the top right corner. The 'References' tab displays the following details:

Study Type	CTIMP-CWoW
Application Type	Application (not requiring SSA)
REC Reference	19/LO/1864
IRAS Project ID	266648
Eudract	2019-000064-21
ISRCTN	
NCT	
Short Title	Fabry study with Fabrazyme and Replagal
Protocol Number	LPS15918

The documents tab shows the submitted documents associated with the application or amendment.

To save a document click on the document which you would like to open, open the file and click 'Save as'. This will save a copy to your personal computer or other device.

Figure 10 – The Documents Tab

The screenshot shows the 'Documents' tab in the HARP Portal. The page title is 'Fabry study with Fabrazyme and Replagal'. Below the navigation tabs, there is a 'Checklist' button and a 'Download Documents' button. A table lists the following documents:

Document Type	Description	Checked In	Document Date	Received Date	Version	Reviewed	Download Documents
Covering letter on headed paper	Cover Letter	22/11/2019	21/11/2019	21/11/2019	V1.0	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only)	Insurance certificate	22/11/2019	30/05/2019	21/11/2019	V1.0	<input type="checkbox"/>	<input checked="" type="checkbox"/>
GP/consultant information sheets or letters	GP Letter	22/11/2019	01/11/2019	21/11/2019	V1.0	<input type="checkbox"/>	<input checked="" type="checkbox"/>
GP/consultant information sheets or letters	Dear Dr letter	22/11/2019	01/11/2019	21/11/2019	V1.0	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Investigator s brochure / IMP Dossier	SmPC: Fabrazyme	22/11/2019	01/12/2018	21/11/2019	V1.0	<input type="checkbox"/>	<input checked="" type="checkbox"/>

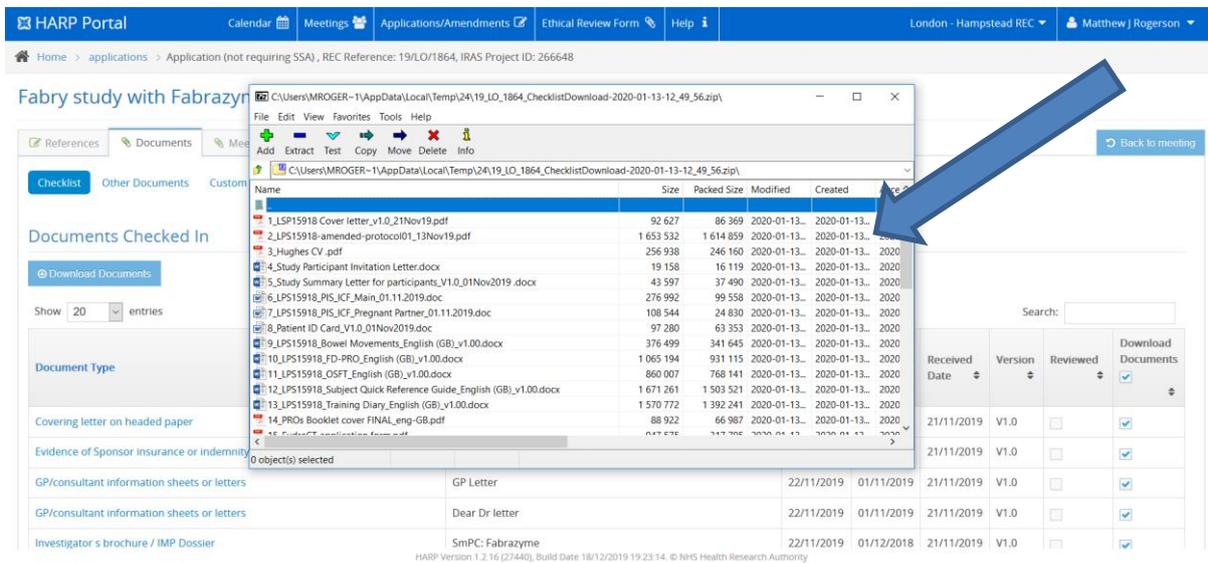
If you would like to download and save all the documents, you can click the blue 'download documents' button. This allows you to save a copy of the applications/amendments and read them later. A zip-file will open in a separate window, which you can save to your device. The documents within the zip-file will always be in a specific order: Cover Letter; IRAS Form; Protocol; Chief Investigator CV, All Participant-facing Documents; All Other Documents.

You can also download a bespoke selection of documents by unchecking any documents you do not wish to download in the download document column.

Figure 11 – How to Download Documents

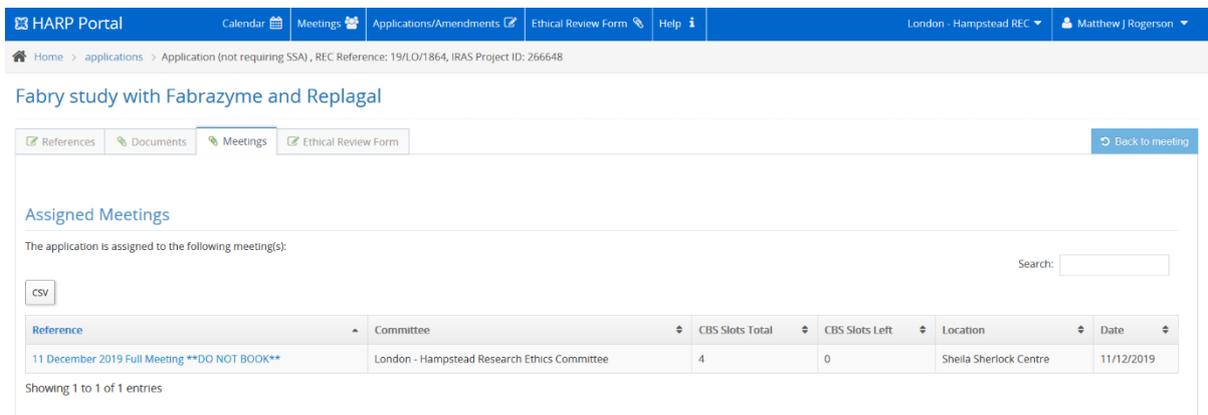
The screenshot shows the same 'Documents' tab as Figure 10, but with a Firefox download dialog box open. The dialog box displays the file '19_LO_1864_ChecklistDownload-2020-01-13-14_17_16.zip' (13.9 MB) and asks 'What should Firefox do with this file?'. The 'Open with' dropdown is set to '7-Zip File Manager (default)'. A red circle highlights the 'Download Documents' checkbox in the table, which is checked. Blue arrows indicate the flow from the 'Download Documents' button to the dialog box.

Figure 12 – The Documents Zip File



The meetings tab shows which meeting/s the application or amendment has been assigned to.

Figure 13 – The Meetings Tab

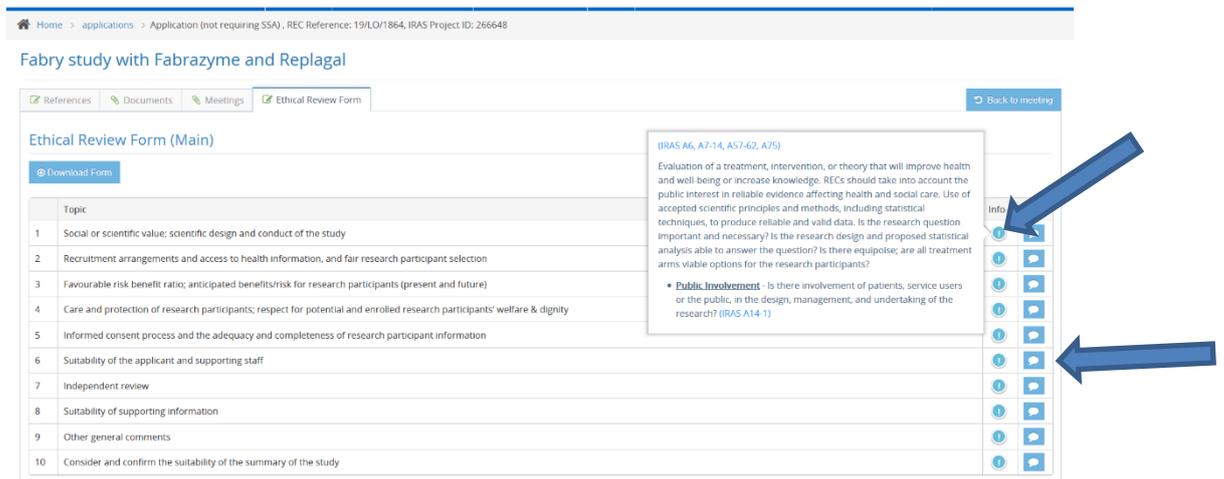


8 Conducting your Ethical Review

When conducting your review, the simplest way to record any comments or questions is via the Ethics Review Form, which is on the right-most tab in the application.

The form contains the ten ethical domains that the review is usually broken down into. You can view prompts on what to look for in each domain (and where to look for it) by hovering your cursor over the 'Info' button by each domain.

Figure 14 – The Ethics Review Form

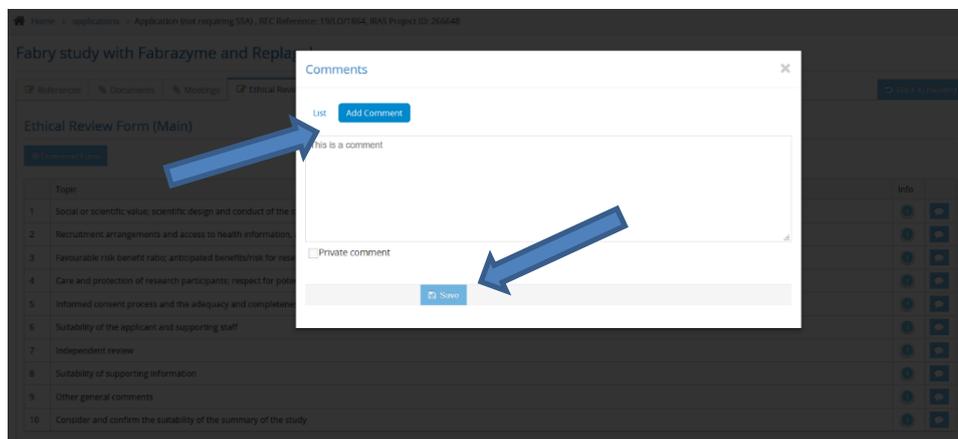


To leave a comment, click on the speech bubble icon by each domain. A 'Comments' box will open. Click on 'Add Comment', leave your comment in the free text box, then click 'Save'. Your comment can then be viewed by the other members of the Committee, and by your Approvals Officer.

If you wish, you can click the 'Private comment' box before clicking save. If you do so, only you will be able to see your comment.

Once you have saved your comment, click on the 'x' in the top right corner of the comment box to close it.

Figure 15 – Adding a Comment



Once you have added and saved your comment, you will see that the speech bubble by the ethical domain has turned from blue to red.

If the speech bubble icon is red this means that a comment has been entered either by yourself or by a different member of the Committee Members can read each other's comments by pressing on the speech bubble icon again to re-open the comments box.

Before the meeting, you can save a copy of the completed ethics review form to your desktop. Clicking on the 'Download Form' button will create a Word document, containing the comments made by all members.

Figure 16 – Downloading the Form

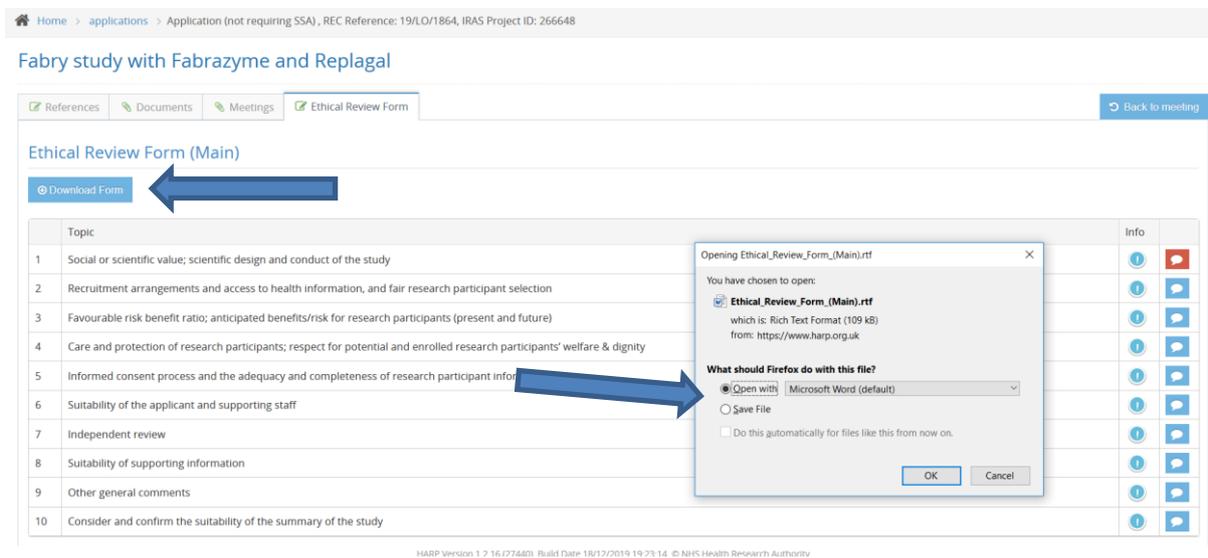
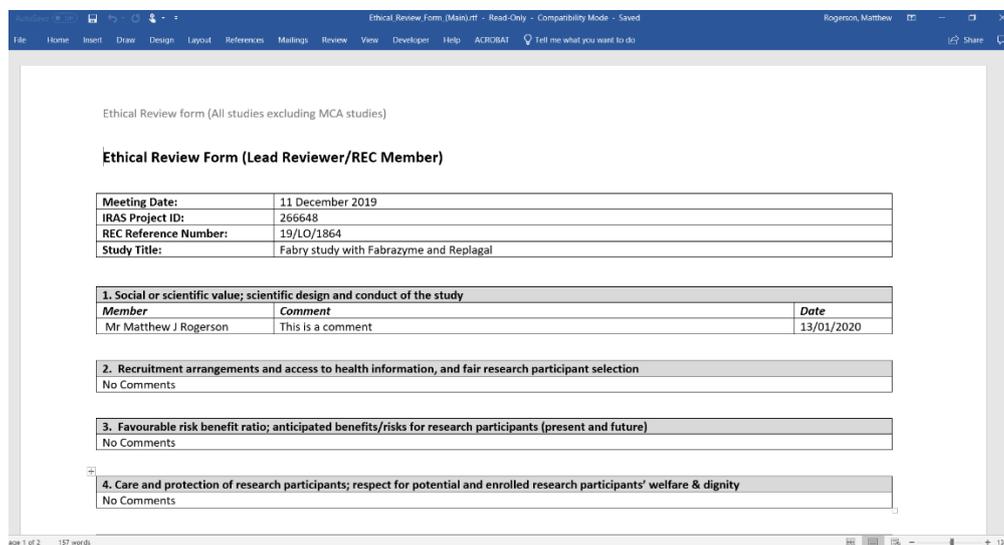


Figure 17 – Ethics Review Form Word Document

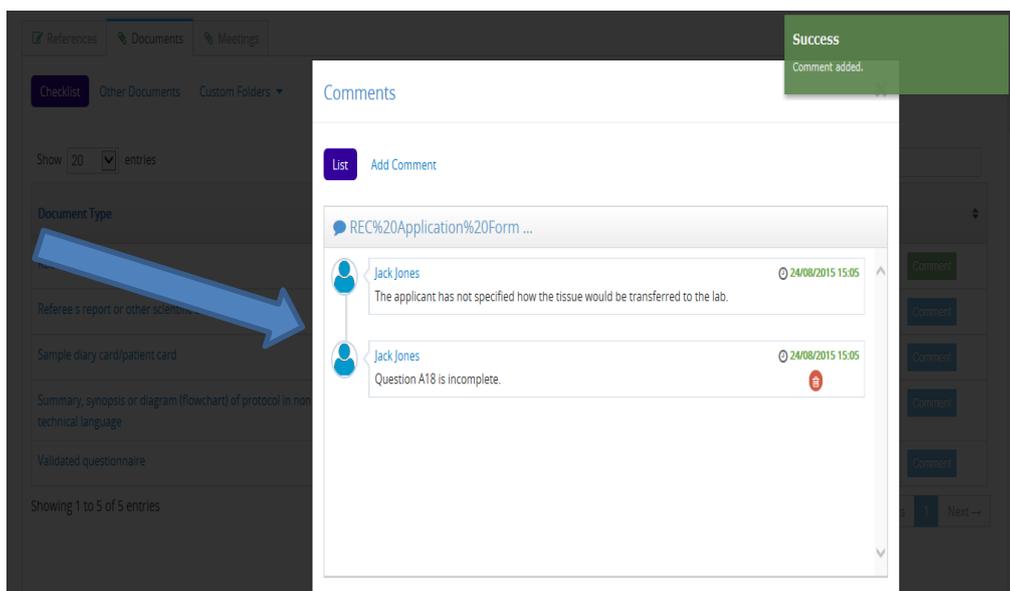


For Amendments, there is no ethical review form. Instead, you can add comments to each document by selecting the 'Comments' button. When you click the button a pop up appears (Figure 17). Once a comment has been added to a document, the 'Comment' button changes from blue to red. You can also view any other comments which have been added by other members or by the Approvals Officer. These comments can only be viewed when you are online.

To add a comment, type into the text box labelled 'Type your message here...' and click 'save'. This comment will be visible to all members of the REC.

Other REC Members and the Approvals Officer will be able to see your comment. Clicking the 'private comment' box means that the comment will not be viewable to other.

Figure 18 – Leaving comments on an Amendment



At the bottom of the page in each amendment, there is an 'Overall Comments' box (Figure 18). Comments entered here can be seen by other members using the portal. You can also choose whether to make the comment viewable to the Approvals Officer via the 'Visible to REC Manager' box.

Figure 19 – The Overall Comments box

List **Add Comment**

this is a test

Visible to REC Manager

Save

Figure 20 – Overall Comments added and visible

Document Type	Description	Checked In	Document Date	Received Date	Version	Reviewed	Download Documents
Covering letter on headed paper	Cover letter	03/12/2019	26/11/2019	26/11/2019		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Investigator's brochure / IMP Dossier	Fulvestrant IB	03/12/2019	01/11/2019	26/11/2019	23	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Notice of Substantial Amendment (CTIMP)		03/12/2019	26/11/2019	26/11/2019		<input type="checkbox"/>	<input checked="" type="checkbox"/>

Showing 1 to 3 of 3 entries

List **Add Comment**

Overall Comments

matthew.j.rogerson@hotmail.co.uk
This is a test

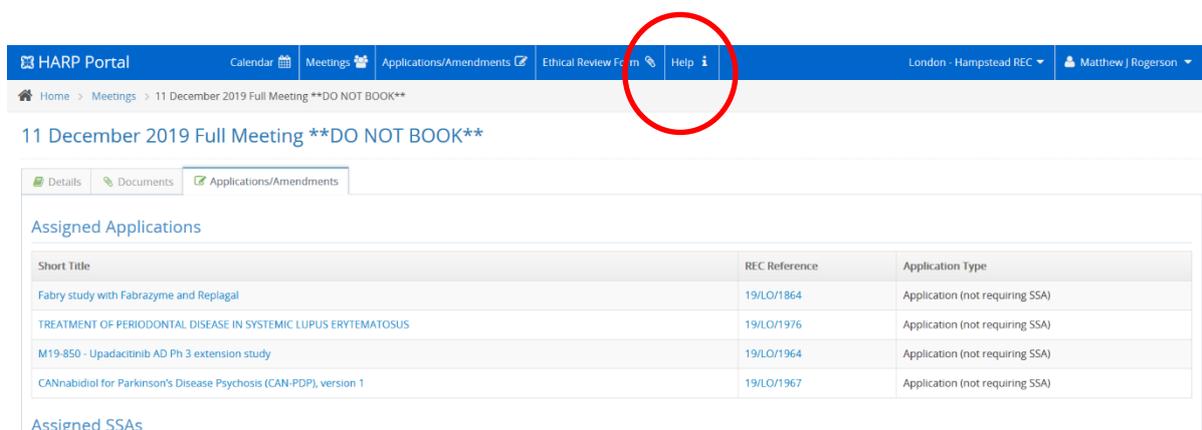
Visible to REC Manager 13/01/2020 15:13

You can, if you wish, add comments directly to the application documents. These will not save to the HARP portal. Please see Appendix A – Annotating Documents for instructions on how to do this.

9 Help

Clicking on the Help icon (on the blue ribbon at the top of the screen) allows you to access a copy of this User Manual and the accompanying Frequently Asked Questions document.

Figure 21 – The Help Icon



The screenshot shows the HARP Portal interface. The top navigation bar is blue and contains several icons: a calendar, a meeting icon, an applications/amendments icon, an ethical review form icon, and a help icon. The help icon, which is a question mark inside a circle, is circled in red. Below the navigation bar, there is a breadcrumb trail: Home > Meetings > 11 December 2019 Full Meeting **DO NOT BOOK**. The main content area has tabs for Details, Documents, and Applications/Amendments. Under the Applications/Amendments tab, there is a section titled 'Assigned Applications' with a table. Below the table is a link for 'Assigned SSAs'.

Short Title	REC Reference	Application Type
Fabry study with Fabrazyme and Replagal	19/LQ/1864	Application (not requiring SSA)
TREATMENT OF PERIODONTAL DISEASE IN SYSTEMIC LUPUS ERYTHEMATOSUS	19/LQ/1976	Application (not requiring SSA)
M19-850 - Upadactinib AD Ph 3 extension study	19/LQ/1964	Application (not requiring SSA)
CANnabidiol for Parkinson's Disease Psychosis (CAN-PDP), version 1	19/LQ/1967	Application (not requiring SSA)

A user instruction video, which talks you through all of the steps outlined in this manual, is available at the following link:

- <https://www.hra.nhs.uk/about-us/committees-and-services/harp/>

10 Appendix A – Annotating Documents

Comments can be added in relation to specific documents in the member portal as described in section 8 above. You may find this particularly useful for Proportionate Review applications and substantial amendments which are reviewed in correspondence. However, for full REC meetings in which you may not have access to an internet connection you may find it more useful to download the documents and insert comments and highlight information directly into the document; and view as a saved document at the REC meeting.

This appendix provides information regarding how to add comments and highlight sections on electronic copies of application documents.

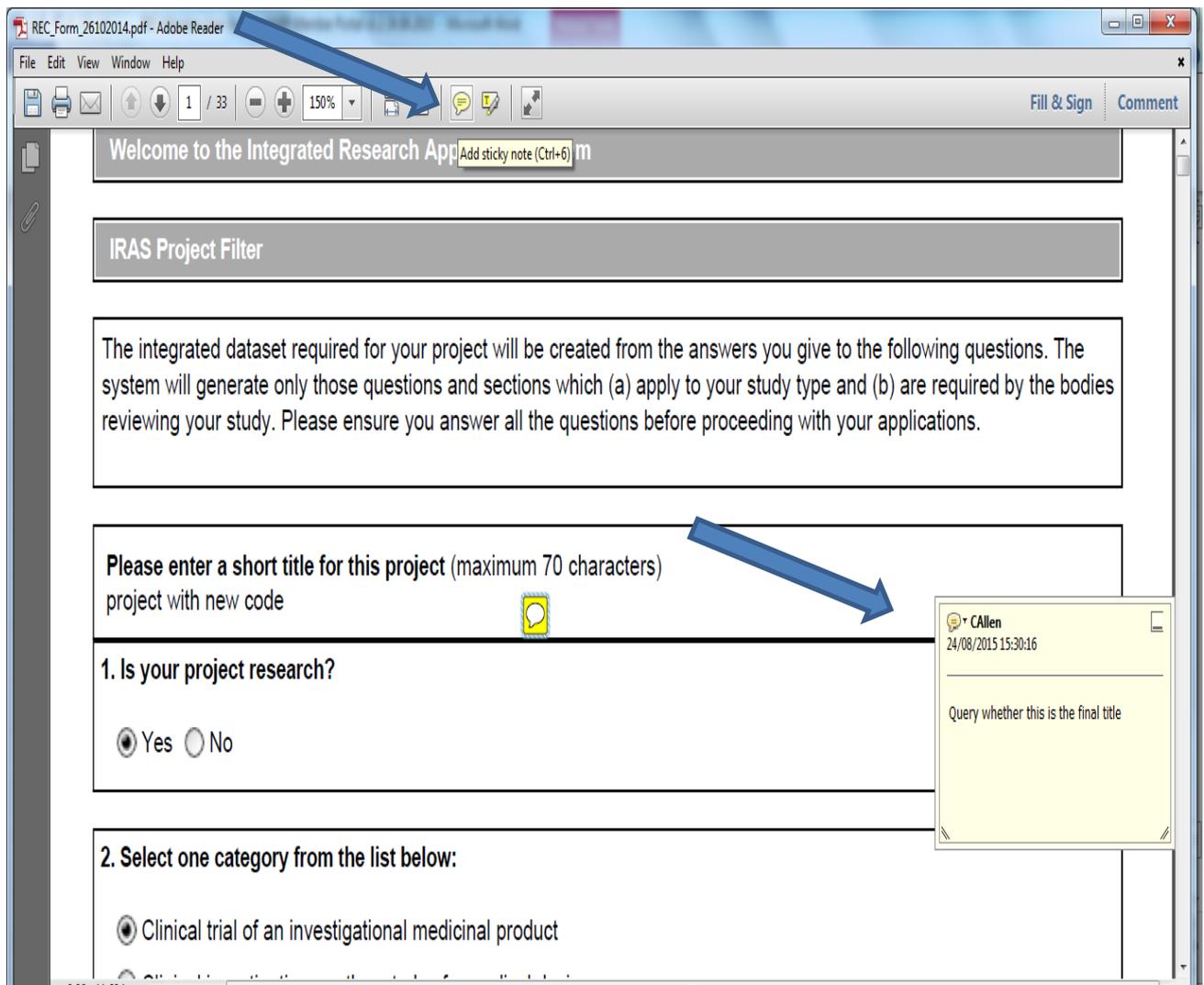
Adding Comments – PDF Documents

There are two ways of adding comments to a PDF document:

- You can right click on the mouse and click 'add sticky note'
- You can click the 'Add sticky note' button in the ribbon at the top of the document

The document including your comments can then be saved to your device to refer to during the meeting.

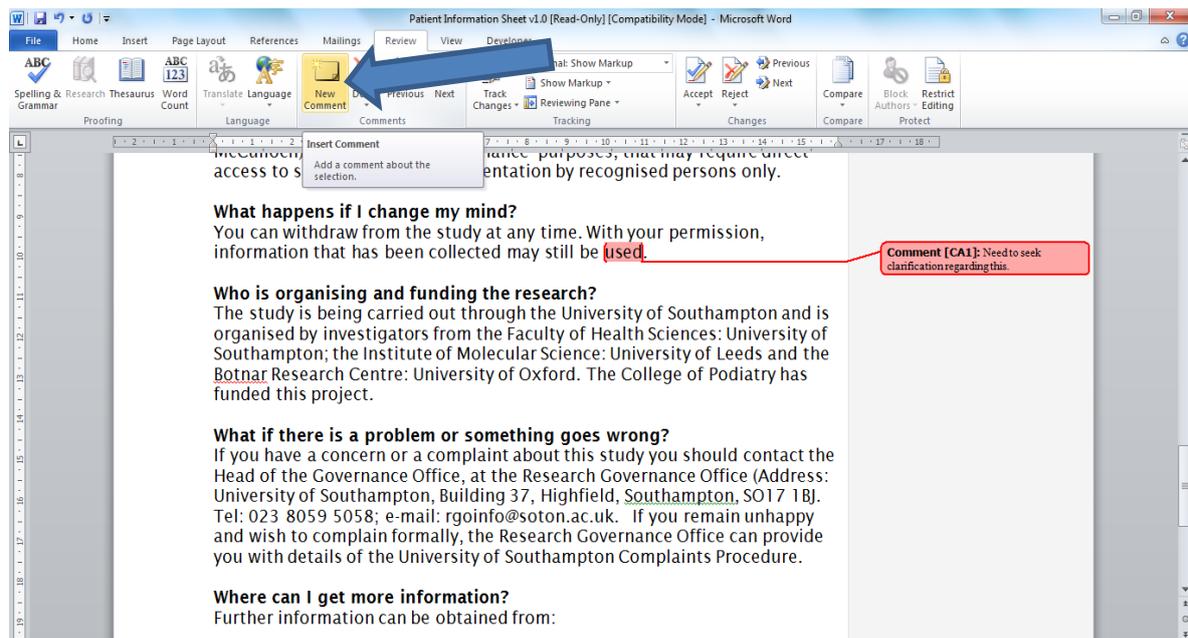
Figure 22 – How to add a comment to a PDF Document



Adding Comments – Microsoft Word Documents

Go to the Review tab and use the 'New Comment' button to insert a comment. The comment will appear in the margin as shown in the example below.

Figure 23 – How to add a comment to a Word Document



Other similar software, such as Libre Office open-source software, will have their own equivalent to the Microsoft Word method. Please consult your software's 'HELP' guides to learn the method for your software.

Highlighting Documents – PDF Documents

Use the highlighting tool, found in the top ribbon, to highlight sections of the application or supporting documents which you may wish to discuss during the meeting.

You can also highlight text by selecting the wording which you wish to highlight, right clicking the mouse and clicking 'Highlight text'

Figure 24 – Highlighting a PDF Document using the ribbon command

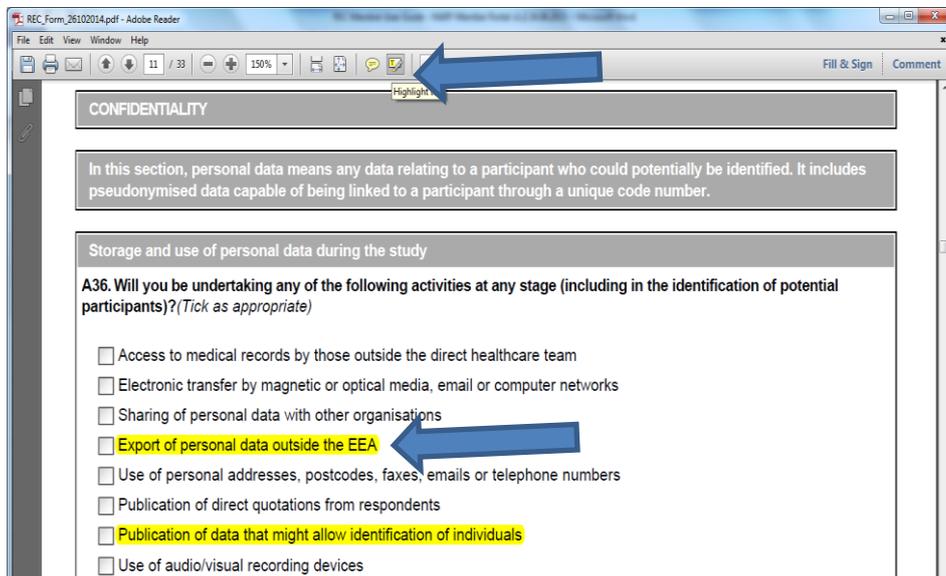
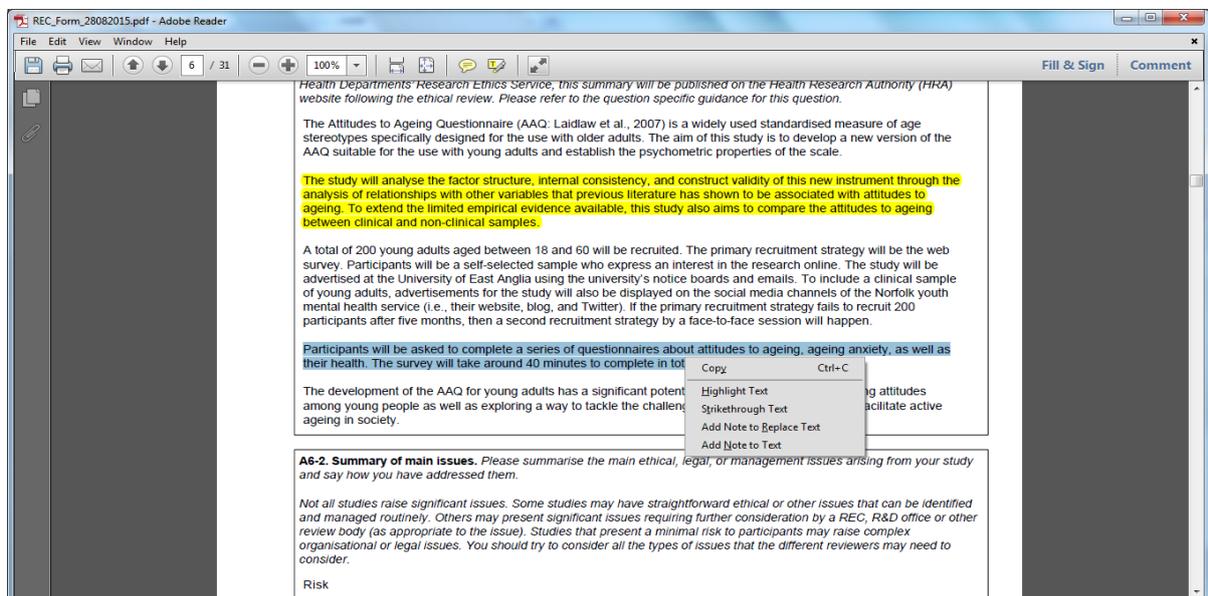


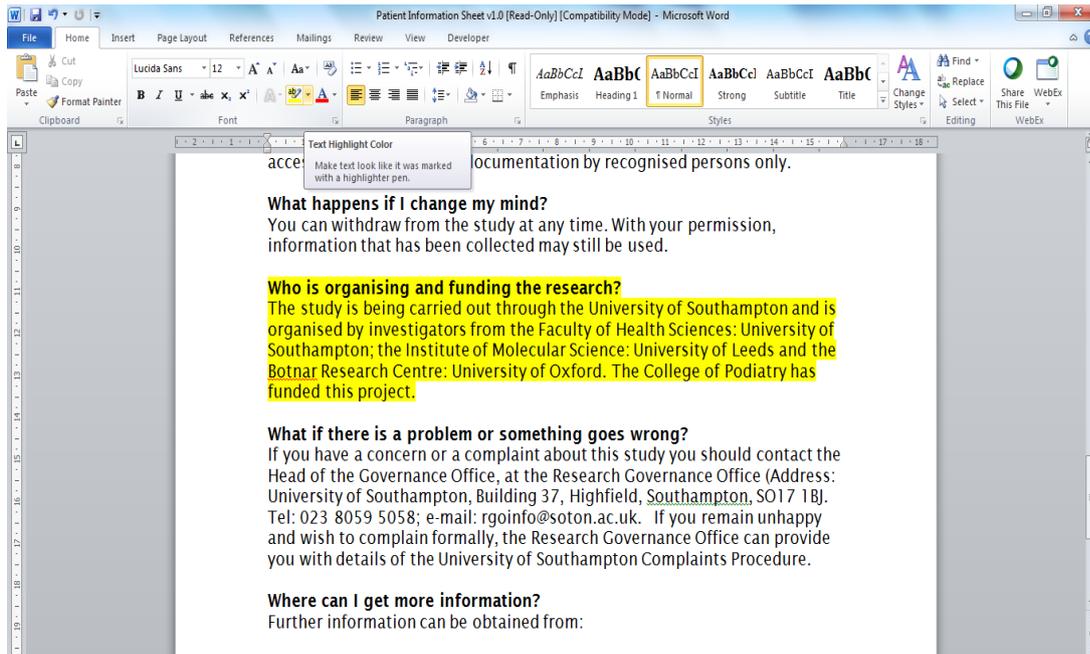
Figure 25 – Highlighting a PDF Document by right-clicking the mouse



Highlighting Documents – Microsoft Word Documents

From the Home tab, click on the highlighter pen to highlight sections of the document. You can then right-click and drag your cursor across the sections of text you wish to highlight

Figure 26 – Highlighting a Word Document

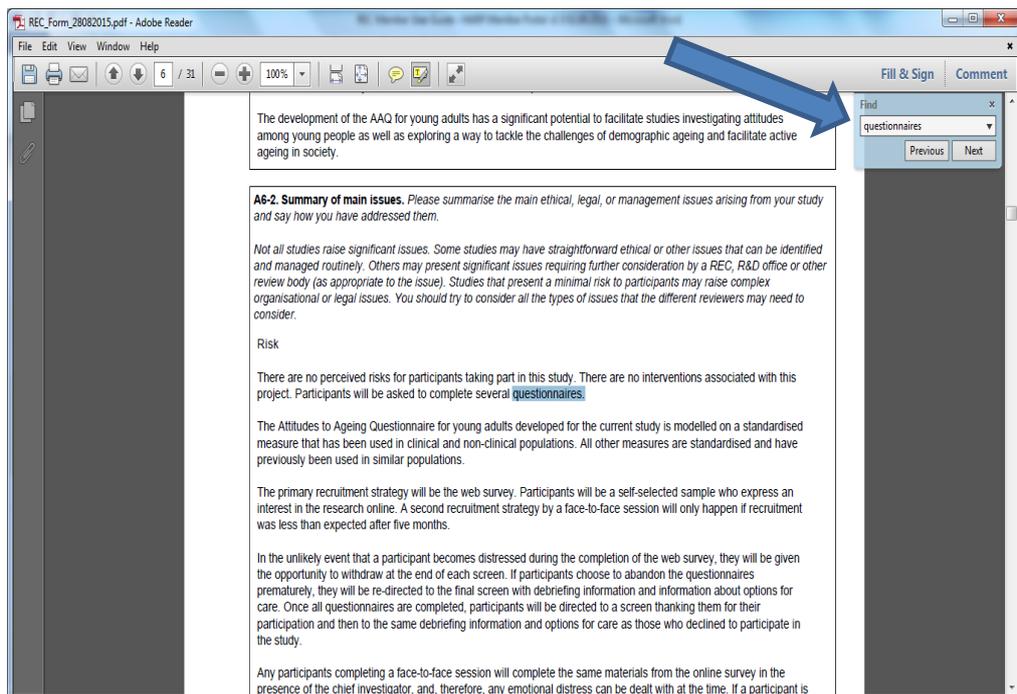


Searching Documents for Key Words

You may find it useful to search documents for key words. Most document types support the same method for doing this. Press the Ctrl key and the F key at the same time. A small navigation box will appear. Enter the word or phrase you wish to search for. Click the Enter/Return key.

The search will instantly find the first occurrence of that word/phrase in your document. If you click Enter/Return again, it will find the next occurrence. You can continue clicking Enter/Return to find every occurrence of the word/phrase in the document.

Figure 27 – Searching a document for key words



Please remember to refer to the Frequently Asked Questions Document and the HARP Member Portal Instruction Video to refresh/reinforce your learning.