



ERA

Ethics Research Administration

Web-based Ethics Application Management System

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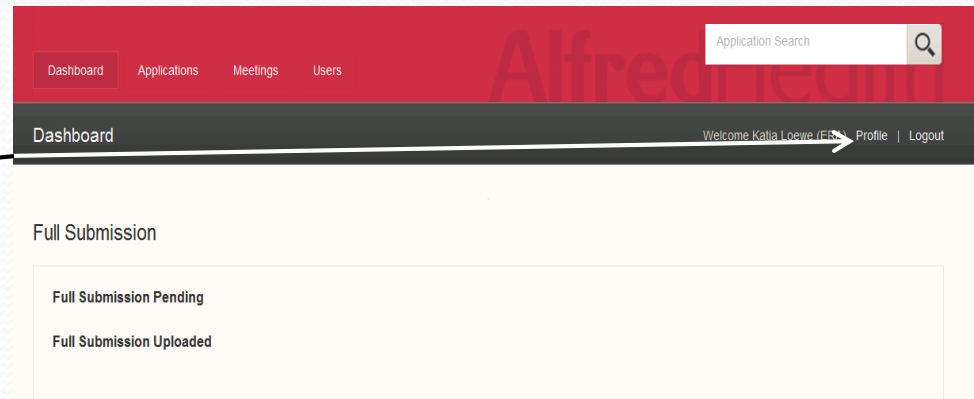
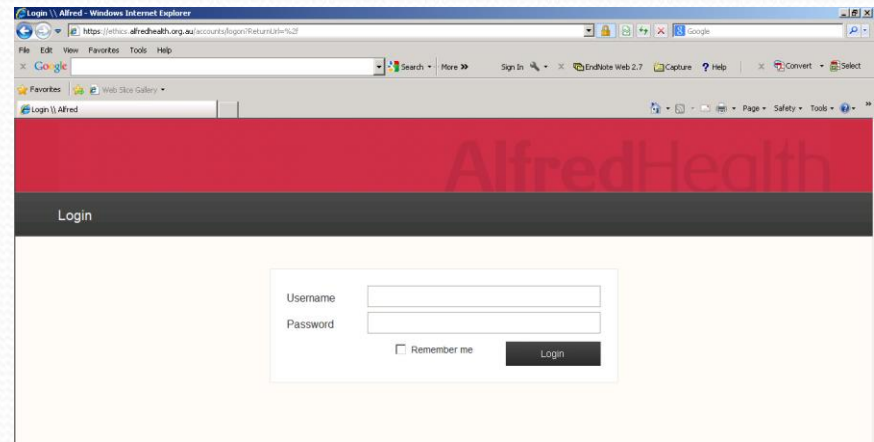
General Information

- ERA (Ethics Research Administration) is an online portal that utilises different statuses to track the progress of a project/amendment application.
- Different user types can access and use the system according to the permissions associated with their user status. For example researchers can upload documents and respond to comments made by reviewers.
- The system will automatically send email notifications to researchers and the Ethics Committee members, alerting them when their next action is required. Items that require attention are also listed on the user's entry page ('Dashboard').
- Access to ERA for new users/to a new project will be organised after the application has been screened, i.e. after project registration has occurred. It is not necessary to contact the office in advance to organise ERA access.
- ERA was developed in collaboration with a software design company with the aim of creating a user-friendly and efficient system for the reviewers and researchers.



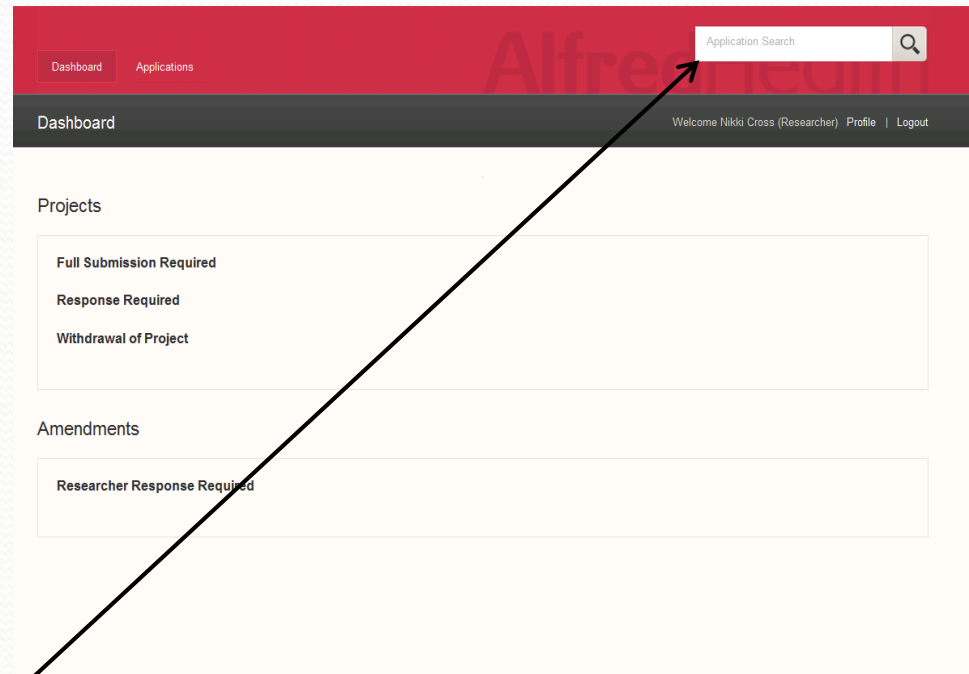
Login

- Enter the web address <https://alfred-era.com.au/accounts/logon?ReturnUrl=%2f> in your internet browser.
- The login screen will appear requiring the username and password to be entered.
- Clicking on 'Login' will take you to your dashboard (entry page).
- Once logged in, you may change your password by clicking on 'Profile' and then on the black button 'Change Password'. After choosing a new password click 'Save'. Keep your password safe!




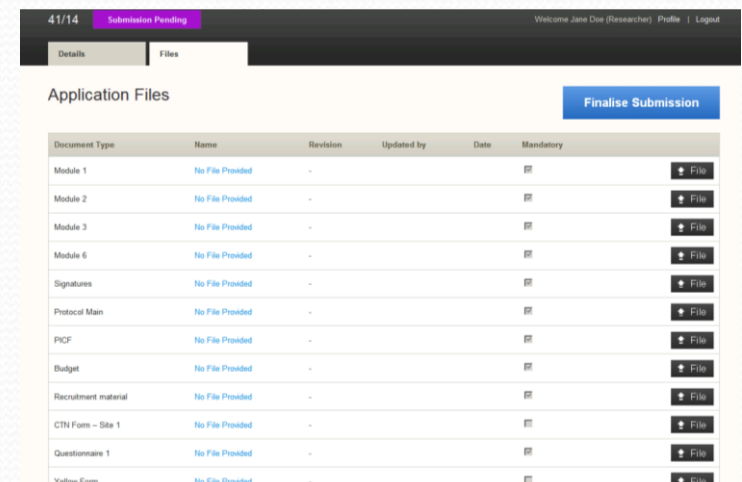
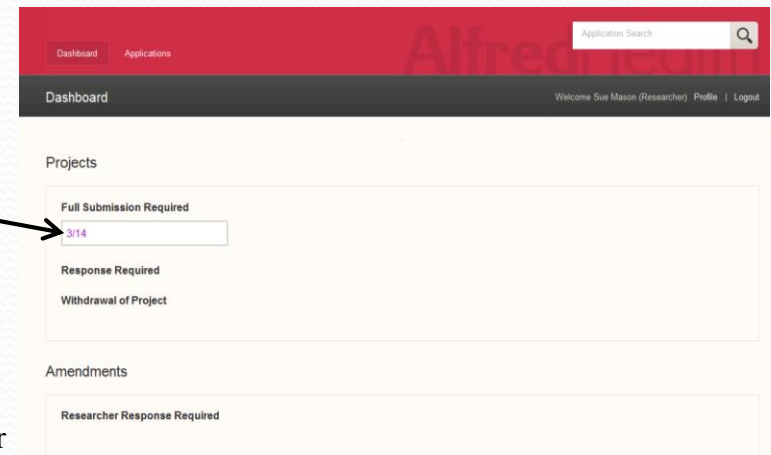
Dashboard

- The Dashboard serves as your “home” screen, alerting you to items that require your attention.
- The dashboard will list projects which:
 - Require a full submission (by the deadline stated on our website and in the initial letter emailed to you)
 - Require a response (when your project has been reviewed and when items need to be addressed before approval can be granted)
 - Have been withdrawn (e.g. when a response has not been received within 3 months after the last communication)
 - Require a response for an amendment submitted
- You can search for any project you are listed on in ERA by typing the project number into the ‘Application Search’ field in the top right corner. The format for project numbers is ‘x/y’, e.g. 1/14.



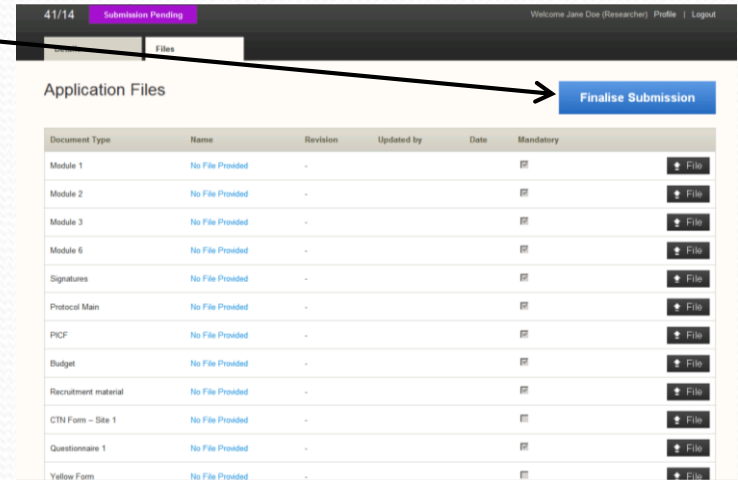
Uploading your full submission

- On your dashboard click on the relevant project number listed under 'Full submission required'.
- This will take you to the project's 'Application container', offering details about the study in the 'Details' tab and allowing you to upload documents in the 'Files' tab.
- In the 'Files' tab the documents to be uploaded are listed. Click on the  File button, select the desired document from its location on your device and click 'Open' and then click 'Upload'.
- Please note that you do not need to upload all documents at once. You may log out and continue your work later. Uploaded documents will be saved in the system automatically.
- Incorrectly uploaded files cannot be removed. Please contact the Ethics Officer/RGO stated in the email alert sent to you.
- If you wish to upload additional documents that are not listed, you will need to contact the relevant Ethics Officer/RGO.



Uploading your full submission (continued)

- To submit your full submission click on **Finalise Submission** (blue button on the top right of page) by the deadline stated in the letter/on the website. Additional documents can not be uploaded once your submission has been finalised.
- Please note that documents which have been indicated as 'Mandatory' need to be uploaded before you can finalise the submission.
- The successful submission is associated with a change in project status. This will be indicated by the project no longer being listed under 'Full submission required'. The system does not separately generate a confirmation message/email notifying you of the successful submission.
- Remember: You can at any time view any application you are listed on by typing the project number in the 'Application Search' field in the top right corner.



41/14 Submission Pending Welcome Jane Doe (Researcher) Profile Logout

Files

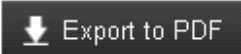
Application Files **Finalise Submission**

Document Type	Name	Revision	Updated by	Date	Mandatory	
Module 1	No File Provided	-			<input checked="" type="checkbox"/>	+ File
Module 2	No File Provided	-			<input checked="" type="checkbox"/>	+ File
Module 3	No File Provided	-			<input checked="" type="checkbox"/>	+ File
Module 6	No File Provided	-			<input checked="" type="checkbox"/>	+ File
Signatures	No File Provided	-			<input checked="" type="checkbox"/>	+ File
Protocol Man	No File Provided	-			<input checked="" type="checkbox"/>	+ File
PICF	No File Provided	-			<input checked="" type="checkbox"/>	+ File
Budget	No File Provided	-			<input checked="" type="checkbox"/>	+ File
Recruitment material	No File Provided	-			<input checked="" type="checkbox"/>	+ File
CTN Form - Site 1	No File Provided	-			<input checked="" type="checkbox"/>	+ File
Questionnaire 1	No File Provided	-			<input checked="" type="checkbox"/>	+ File
Yellow Form	No File Provided	-			<input checked="" type="checkbox"/>	+ File



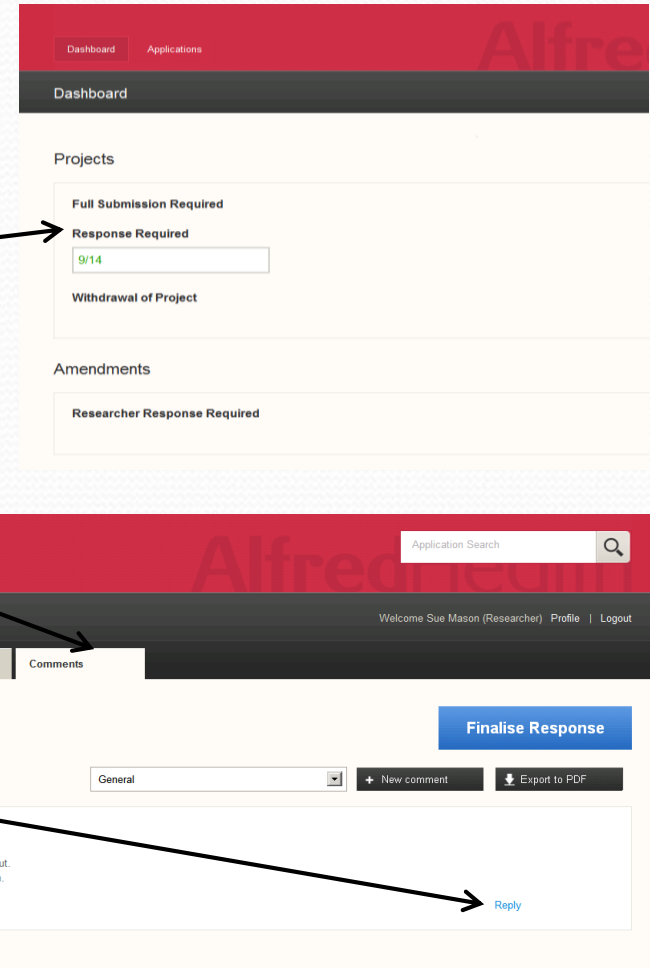
TheAlfred

Response required

- When changes to the application are required, you will receive an email alert asking you to log on and respond to items that require clarification, revise application documents as requested and/or upload additional documents.
- The projects for which changes are required are listed under 'Response required' on your dashboard.
- Comments made by the reviewers and the Office can be viewed by clicking on the 'Comments' tab.
- All comments can be exported to a PDF file by clicking on .



For sponsors: Please note that the PDF does not contain an official signature.

- You may respond to a comment by clicking on 'Reply'. Please type your response into the pop-up window and click 'Save comment'. Your response will appear underneath the relevant comment for reviewers and the Ethics Office to see.
- Please note that only one reply per comment is permitted, and that the reply cannot be edited once saved.



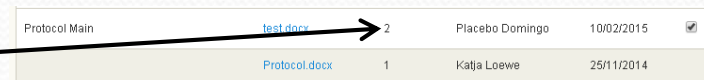
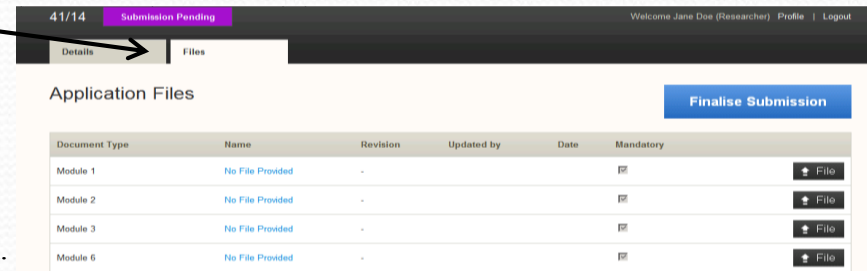
The screenshot displays the 'The Alfred' system interface. At the top, a red navigation bar contains 'Dashboard' and 'Applications' tabs. Below this, a 'Dashboard' section shows 'Projects' with a 'Response Required' status for '9/14' and a 'Withdrawal of Project' option. An 'Amendments' section shows 'Researcher Response Required'. A second screenshot below shows the 'Application Comments' page for '9/14', which is 'Awaiting Researcher Response'. It features a 'Details' tab, a 'Comments' tab, and a 'Finalise Response' button. A comment from 'PICF - (Revision 1)' is shown, with a 'Reply' link. A search bar and 'Export to PDF' button are also visible.

Response required (continued I)

- When asked to revise a document, please go to the 'Files' tab.
- Documents, which you have been asked to (re)submit, will have the  File button displayed. Select the desired document from its location on your device, click 'Open' and then click 'Upload'.
- Documents without the  File button cannot be uploaded again.

Contact the Ethics Officer/RGO stated in the alert email if you need to re-submit any documents for which the upload function is disabled.

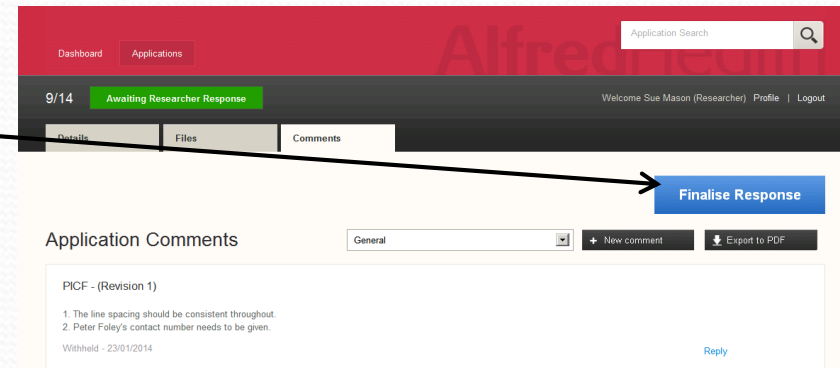
- If you wish to upload additional documents that are not listed, you will need to contact the relevant Ethics Officer/RGO.
- Do not upload a document against a non-matching document type, e.g. uploading a radio advertisement against 'Advertisement - Poster'.
- Do not upload different documents on top of each other, e.g. uploading the main PICF and the pregnancy follow-up PICF against 'PICF' because there is no 'spot' to upload the pregnancy follow-up PICF separately. Ask the relevant Ethics Officer/RGO to open the additional 'spots' required.
- Different versions of one document type are stored on top of each other with the latest version on top. Clicking on 'Revision' will show previously submitted versions of a document type (expand/retract function).



Document Type	Name	Revision	Updated by	Date	Checkmark
Protocol Main	test.docx	2	Placebo Domingo	10/02/2015	
	Protocol.docx	1	Katja Loewe	25/11/2014	

Response required (continued II)

- Please upload documents with changes tracked. We do not require clean versions to be submitted.
- Please note that the **PICF needs to be submitted in Word format and that the submission of scanned documents (apart from signatures) is discouraged.**
- After uploading all required documents and responding to all comments, click on **Finalise Response** in the 'Comments' tab .
- You will not be able to reply to comments or upload documents once your response has been finalised.
- Once successfully finalised the project will disappear from your dashboard under 'Response required'. The system does not separately generate a confirmation message/email notifying you of the successful submission.
- You will be notified via email alert should further changes be required.
- Remember: You can at any time view any application you are listed on by typing the project number in the 'Application Search' field in the top right corner.



Ethics approval

- Once you have received an email alert that your project has been approved, the 'Certificate of Approval' can be downloaded from the 'Files' tab.
- Please note the following:
 - **For all studies involving Alfred Health sites (including streamlined applications submitted via SERP or NMA):**
Please note that you cannot commence your project at Alfred Health sites until it has also received Alfred Health governance authorisation. Please do not begin at any Alfred Health site until then.
 - **For all studies involving other sites/institutions:**
Please check with those sites/institutions regarding any governance authorisation requirements they may have for this project.



Governance Authorisation/Endorsement of low-risk projects

- **For projects not submitted via SERP or NMA:**

Once governance authorisation from Alfred Health has been granted, an email alert will be sent to notify you that your research may commence at Alfred Health sites. No further action is required.

- **For streamlined projects submitted via SERP or NMA:**

Once governance authorisation from Alfred Health has been granted, an email alert will be sent to notify you that your research may commence at Alfred Health sites. The SSA authorisation letter can be downloaded from the 'Files' tab in the project's 'Application Container'.

- **For low-risk projects:**

You can start your low-risk project as soon as it receives ethical approval. You will receive another alert, once your project has been endorsed by the Ethics Committee. That alert is a mere notification and does not require further action.



Amendments – General information

- Please note the following:
 - **For projects considered at 2014 Ethics Committee meetings and onwards and for accepting projects submitted 2014 and onwards**
Amendments are submitted via ERA. Refer to the following pages for more information. If you do not have an ERA login yet, [contact](#) the Office of Ethics and Research Governance.
 - **For projects considered at Ethics Committee meetings prior to 2014**
Email the amendment form and supporting documents to research@alfred.org.au.
The submission of these amendments via ERA may be implemented at a later stage. Please check our website for updates.
- To upload a revised version of a previously submitted document, upload the document with changes tracked.
- Please note that the **PICF needs to be submitted in Word format and that the submission of scanned documents (apart from signatures) is discouraged.**
- Do not submit amendments for **accepting projects** unless the **approval certificate from the reviewing HREC** has been uploaded.

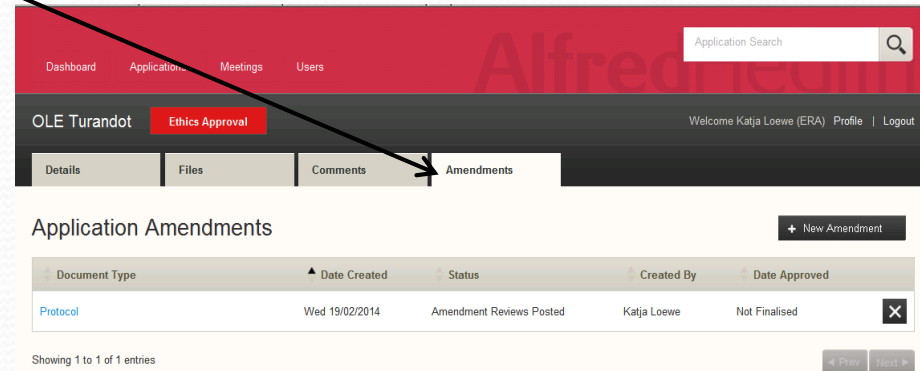
Amendments – Accompanying information

- After your project has received ethical approval, an 'Amendments tab' will be displayed in the project's 'Application container'.
- To submit a new amendment, go to the 'Amendments' tab and click on **+ New Amendment**.

- A new screen will be displayed.
- After stating the amendment type (e.g. Change to research personnel, Change to protocol, Addition of advertisement) and providing a short description, click **Save**.

If an error message occurs when trying to save the amendment, reduce the number of characters for amendment type, as these are limited.

- You also need to save when making changes to either field (amendment type or description).
- To upload the files relating to your amendment application, a 'spot' for each document to be uploaded needs to be created.
- There are three buttons available to create 'spots' – depending on whether the document to be uploaded is a revision of a previously submitted document or is a new document that either is listed in a drop-down list of commonly submitted files or, when not listed, can be entered via a 'free text' box.
- The different upload options are detailed on the next slides.

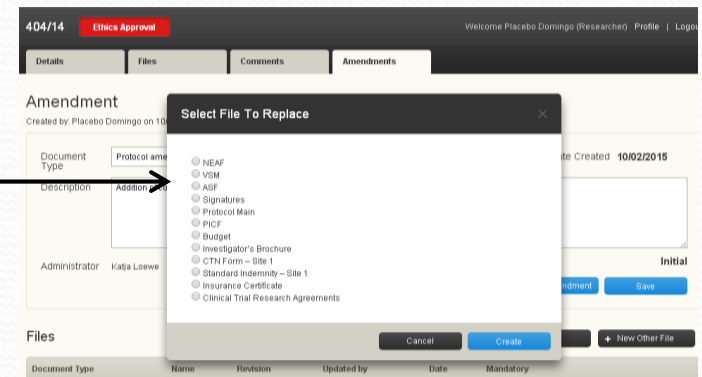


Amendments – Upload of Files

- **+ Replace Existing**

To upload a revised version of a previously submitted document (e.g. protocol, PICF).

Select the document type from the displayed list of previously submitted documents (generated from documents contained in the 'Files' tab) and click **Create**.



Amendments – Upload of Files (continued I)

- **+ New File**

To upload a new document from a drop-down list. The list has been compiled to capture commonly submitted documents. Precise labelling of the document to be uploaded is important to facilitate the review.

Select the appropriate document type and click **Create**.

If the relevant document type is not listed, please use the

- **+ New Other File**

button (see next slide).

The screenshot shows the 'Amendment' form in a system. The 'Document Type' dropdown menu is open, displaying a list of document types including: Advertisement - Poster, Advertisement - Fair, Advertisement - Other, Advertisement - Radio, Advertisement - Social Media, Advertisement - Website, ACP, ATRIO reference, Budget, Confidential Hospital Authorization, Clinical Investigation Plan, Clinical Trial Research Agreements, CTR, CTN Form - Site 1, CTN Form - Site 2, CTN Form - Site 3, CTR - Non-standard Template, and CTR & Intensity Checklist. The 'Create' button is visible at the bottom right of the form.



TheAlfred

Amendments – Upload of Files (continued II)

- **+ New Other File**

To upload a new document not listed in the drop-down menu.

Precise labelling of the document to be uploaded is important to facilitate the review.

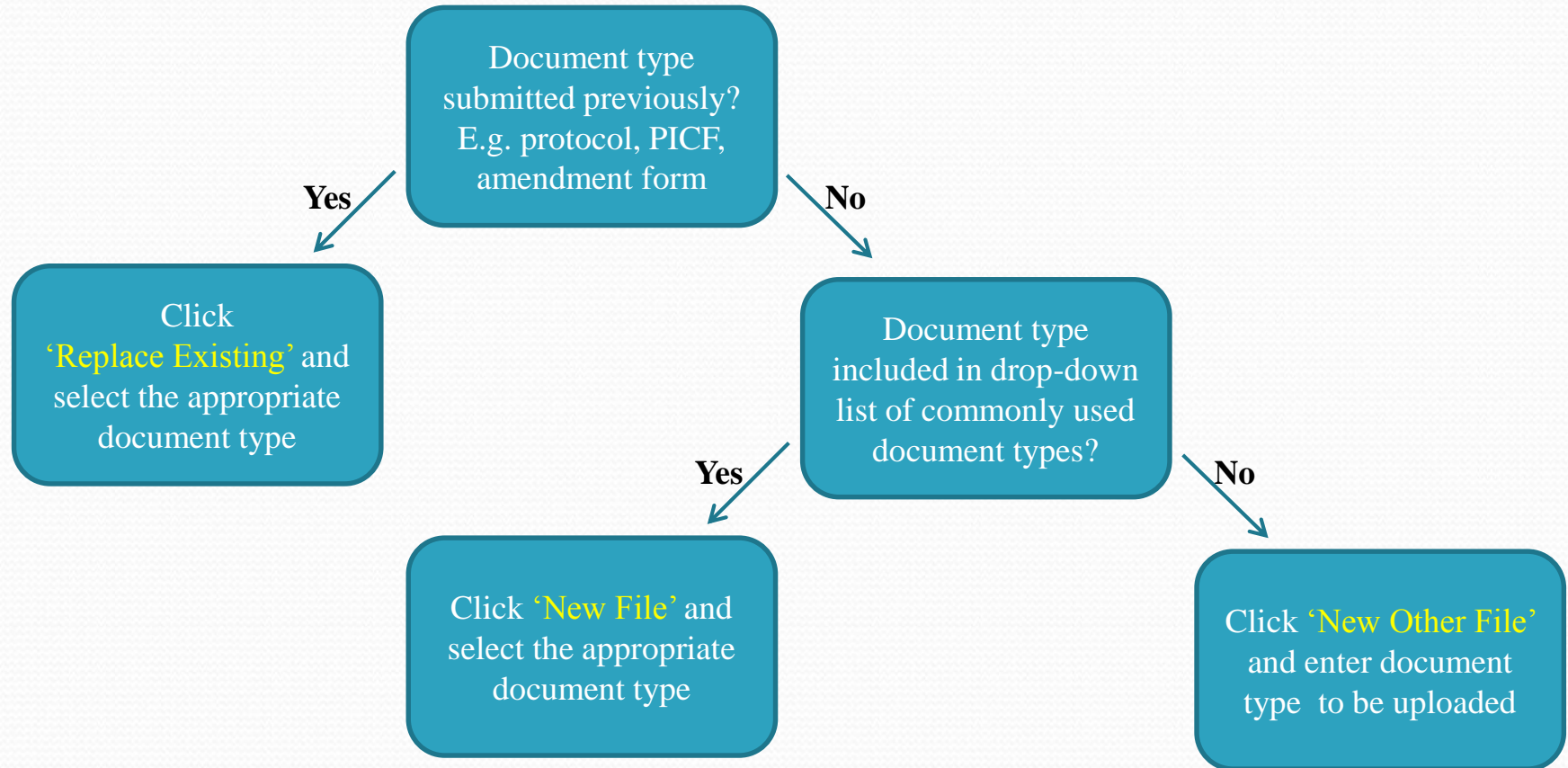
Simply type the document type into the data field and click **Create**.

- Any form (amendment, change to research personnel, IB/DSUR form) should be submitted via this option.


The screenshot shows the 'Amendment' form in a web application. The form has tabs for 'Details', 'Files', 'Comments', and 'Amendments'. The 'Amendments' tab is active. The form contains fields for 'Document Type', 'Protocol amendment', 'File Type', 'Is Mandatory?', 'Description', and 'Addition of'. A 'New File' dialog box is open, showing a text input field with 'Amendment form' and a 'Create' button. An arrow points from the text 'Simply type the document type into the data field' to the 'File Type' field in the form. The form also has a 'Submit Amendment' button and a 'Save' button. The 'Files' section at the bottom has buttons for 'Replace Existing', 'New File', and 'New Other File'.

Amendments – Upload of Files

Quick decision flow chart – Which upload button to use?






Amendments – Upload of Files (continued III)

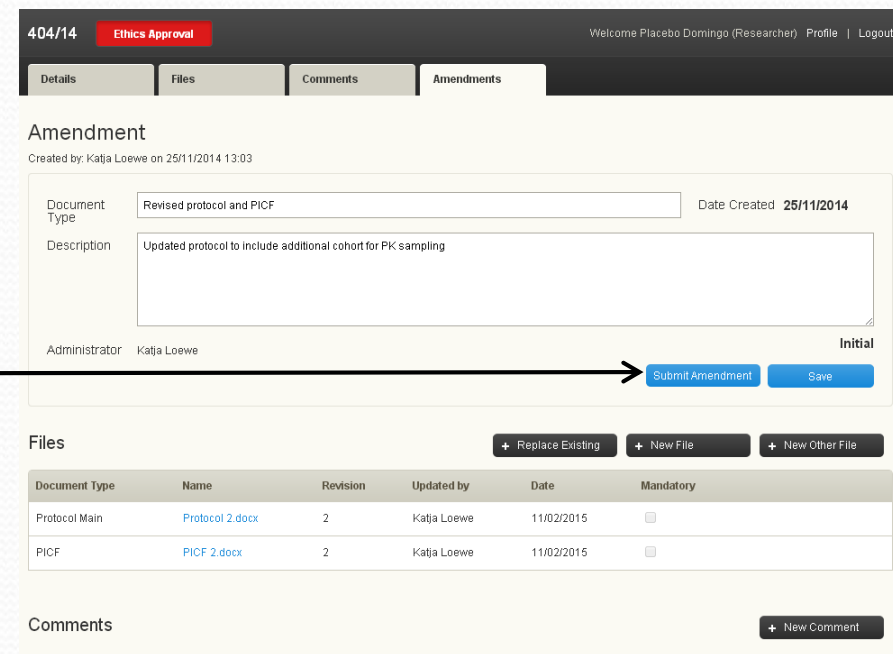
- To upload files click on the  File button, select the desired document from its location on your device and click ‘Open’ and then click ‘Upload’.
- All documents submitted for an amendment will be copied across into the ‘Files’ tab, once the amendment is approved. This way the latest approved version of each document can always be found in ‘Files’. If there are several revisions of one document type, only the latest revision, i.e. the document approved as part of the amendment application, gets copied across into ‘Files’. The different revisions are stored on top of each other and can be accessed by clicking on ‘Revision’ (expand/retract function).
- When submitting subsequent amendments please check whether documents you wish to upload have been submitted previously and are thus available in the list under ‘Replace Existing’. For example ‘Amendment form’ will already be listed if a previous amendment has been approved; therefore ‘Amendment form’ should be chosen from the list when selecting ‘Replace Existing’ rather than adding it again via ‘+ New Other File’.
- After uploading a document, hovering over the document type shows which upload option has been selected.
- If an error is made during the upload process, contact the person listed under ‘Administrator’. It might become necessary to delete a particular document type or the entire amendment.



Document Type	Name
Protocol Replacement	Protocol 2.docx
PICF	PICF 2.docx

Amendments – Submission

- If you need to add a comment click , enter your comment and click .
- You do not need to upload all documents/post all comments at once. You may log out and continue your work later. Uploaded documents/posted comments will be saved in the system.
- Once you are ready to submit your amendment, click .
- Please note that you will not be able to upload documents or post comments, once you have submitted your amendment.



The screenshot displays the 'Ethics Approval' system interface. At the top, there's a header with '404/14' and 'Ethics Approval'. Below this, a navigation bar includes 'Details', 'Files', 'Comments', and 'Amendments'. The 'Amendments' section is active, showing an 'Amendment' form. The form includes a 'Document Type' field with 'Revised protocol and PICF', a 'Date Created' field with '25/11/2014', and a 'Description' field with 'Updated protocol to include additional cohort for PK sampling'. The 'Administrator' is listed as 'Katja Loewe'. Below the form, there are 'Submit Amendment' and 'Save' buttons. An arrow points from the 'Submit Amendment' button in the text to the button in the interface. Below the form, there's a 'Files' section with buttons for 'Replace Existing', 'New File', and 'New Other File'. A table lists the files: 'Protocol Main' (Protocol 2.docx, Revision 2, Updated by Katja Loewe, Date 11/02/2015, Mandatory checkbox) and 'PICF' (PICF 2.docx, Revision 2, Updated by Katja Loewe, Date 11/02/2015, Mandatory checkbox). At the bottom, there's a 'Comments' section with a 'New Comment' button.

404/14 Ethics Approval Welcome Placebo Domingo (Researcher) Profile | Logout

Details Files Comments Amendments

Amendment
Created by: Katja Loewe on 25/11/2014 13:03

Document Type: Revised protocol and PICF Date Created: 25/11/2014

Description: Updated protocol to include additional cohort for PK sampling

Administrator: Katja Loewe Initial

Submit Amendment Save


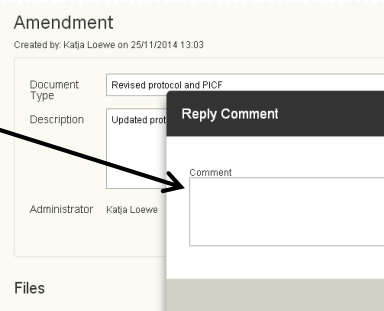

Files

+ Replace Existing + New File + New Other File

Document Type	Name	Revision	Updated by	Date	Mandatory
Protocol Main	Protocol 2.docx	2	Katja Loewe	11/02/2015	<input type="checkbox"/>
PICF	PICF 2.docx	2	Katja Loewe	11/02/2015	<input type="checkbox"/>

Comments + New Comment

Amendments – Response required

- If the reviewers request changes to be made to the amendment application, you will receive an email alert asking you to log in and address the items queried. Amendments requiring a response will be listed on your dashboard. Clicking on the relevant item opens up the corresponding amendment. 
- Respond to comments made by clicking [Reply](#), then type in your response and click [Save Comment](#). 
- Please note that only one reply per comment is permitted, and that the reply cannot be edited once saved.
- To upload files you have been requested to (re-)submit, please click  [File](#).
- If you need to submit/revise additional documents other than the ones indicated, please contact the person listed under 'Administrator'.
- After uploading all required documents and responding to all comments, click on [Finalise Response](#). You will not be able to reply to comments or upload documents, once your response has been finalised.
- Once successfully finalised, the project will disappear from your dashboard.

The system does not separately generate a confirmation message/email notifying you of the successful submission.

be required.

Amendments – Approval/Authorisation

- Once you have received an email alert that your amendment has been approved, the amendment approval certificate/authorisation letter is available for download from the ‘Amendments’ tab. Click on the corresponding amendment, find the approval certificate/authorisation letter listed under ‘Files’ and then click on the document to open/save it.
- The latest version of all documents relating to an amendment application (i.e. the final version of each document) will also be copied into the 'Files' tab of the project's 'Application Container' along with the amendment forms and approval certificate/authorisation letter.