



ERA

Ethics Research Administration

Web-based Ethics Application Management System

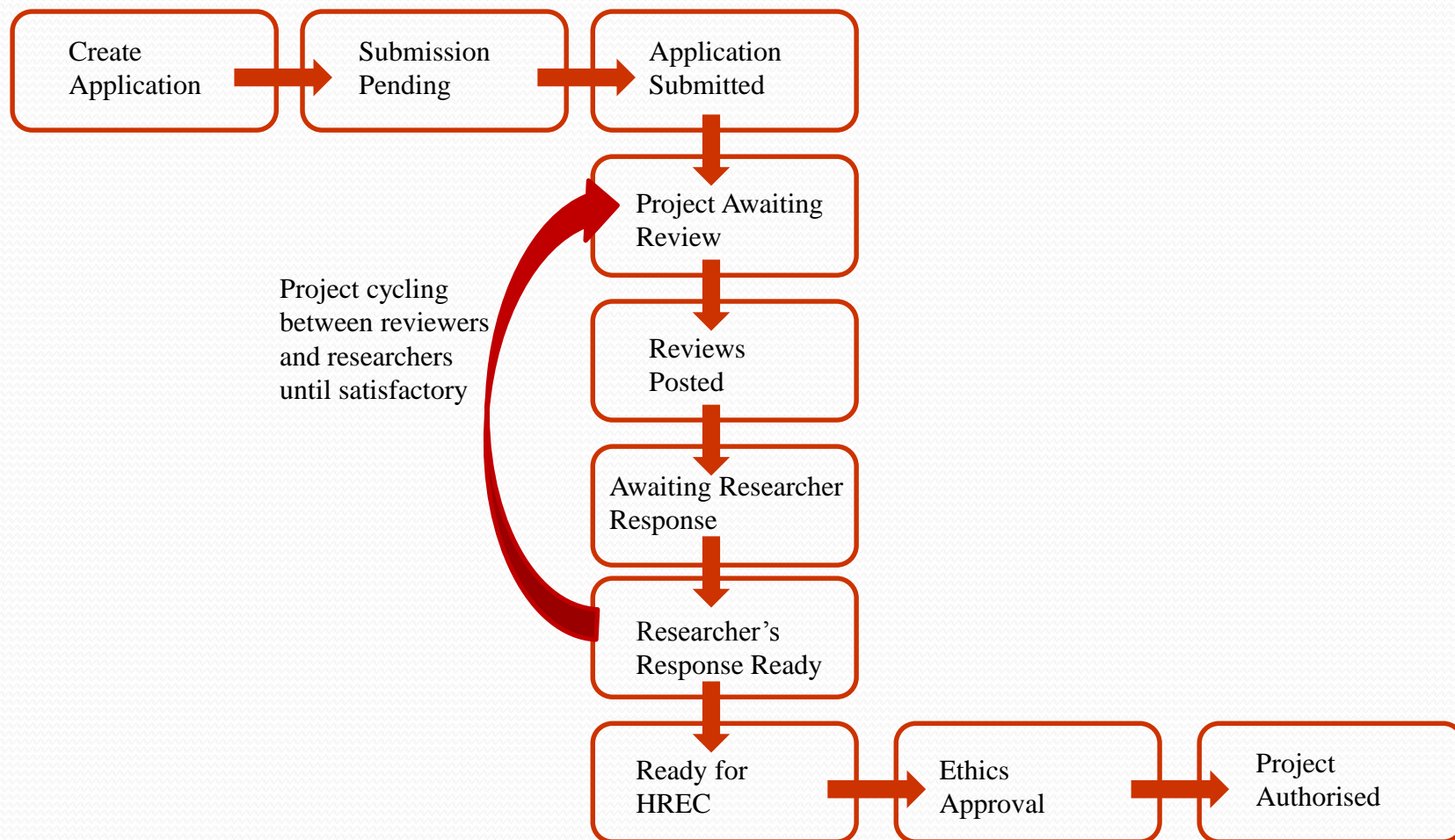
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General Information

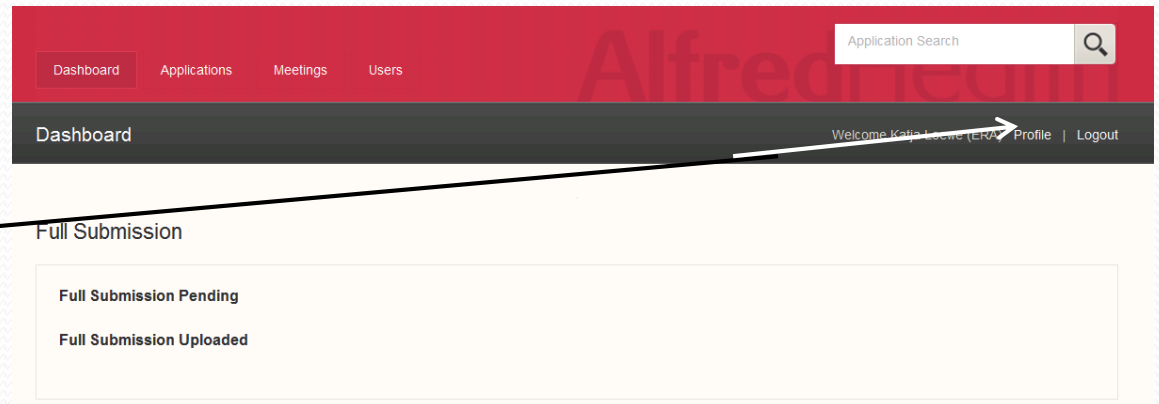
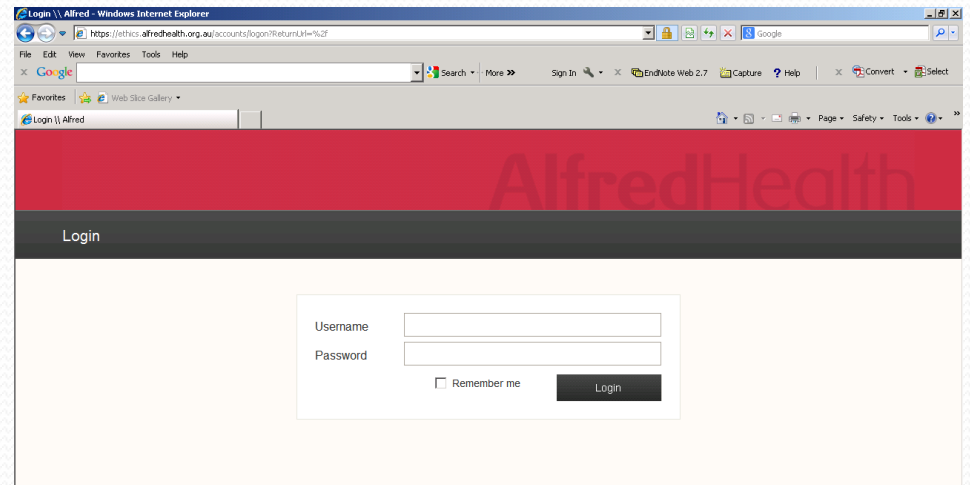
- ERA (Ethics Research Administration) is an online portal that utilises different statuses to track the progress of a project/amendment application.
- Different user types can access and use the system according to the permissions associated with their user status. For example researchers can upload 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').
- 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.

General Information (continued)



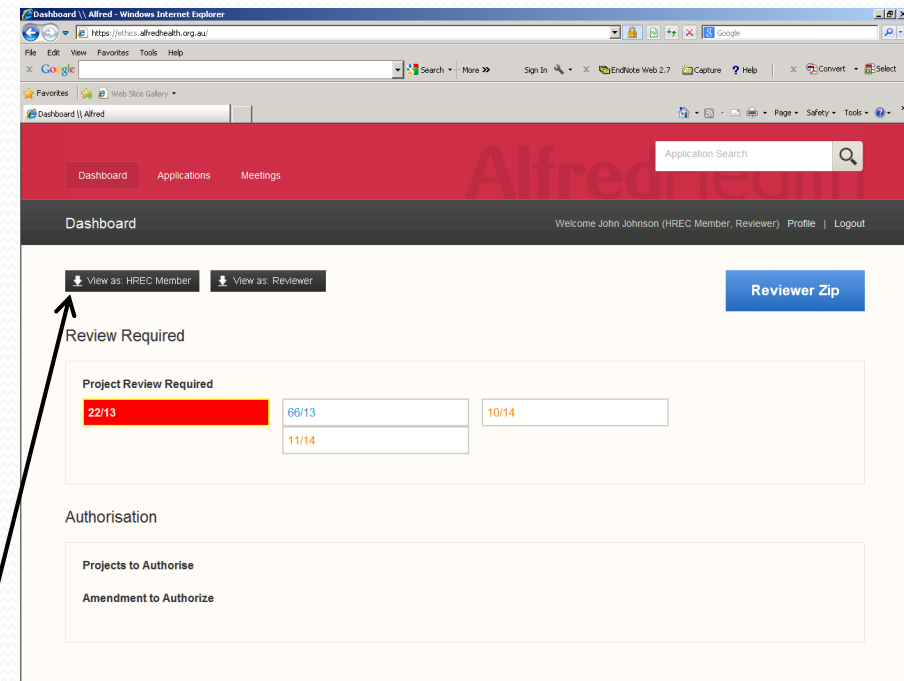
Login

- 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. Both would have been created by the office and sent to you via email.
- Clicking on 'Login' will take you to your dashboard (see next 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!



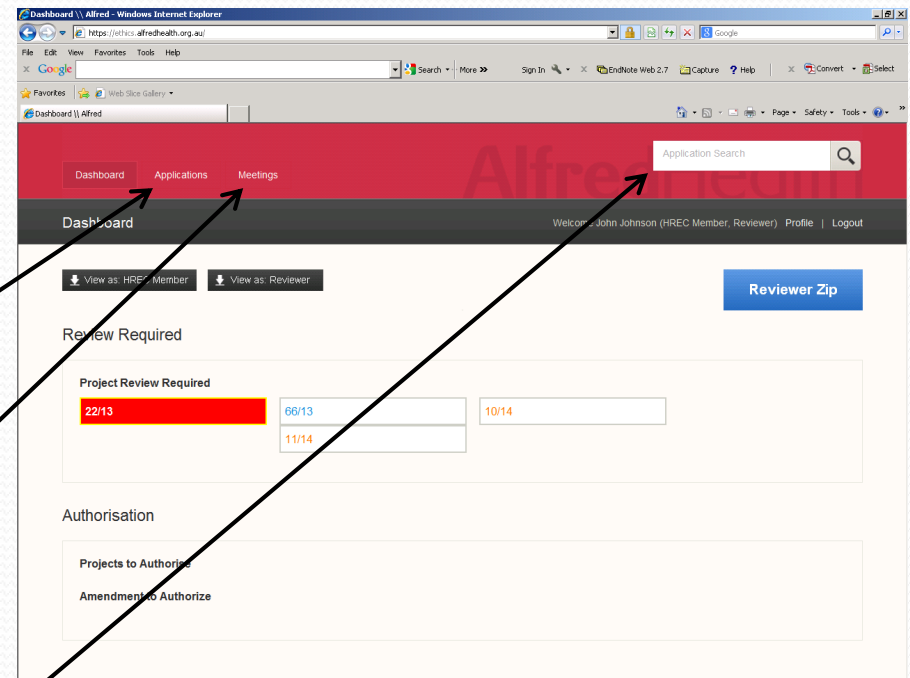
Dashboard

- After logging in, your ‘dashboard’ will be displayed. This will serve as a notification board, displaying items requiring your review:
 - Projects
 - Researcher responses
 - Amendments
 - Monitoring items (not implemented yet)
- All items requiring your attention are displayed on your dashboard. Until all processes have been put in place, you will also receive items to review outside of ERA (e.g. monitoring) via email.
- You have been assigned the user categories ‘Reviewer’ as well as ‘HREC member’ and/or ‘RRC Member’. Clicking on either will display a slightly different screen. ‘Reviewer’ will show the projects for review, while either ‘Member’ category will show amendments and later on monitoring as well. (FYI: Projects and amendments for authorisation are relevant to the Director of Research only.)



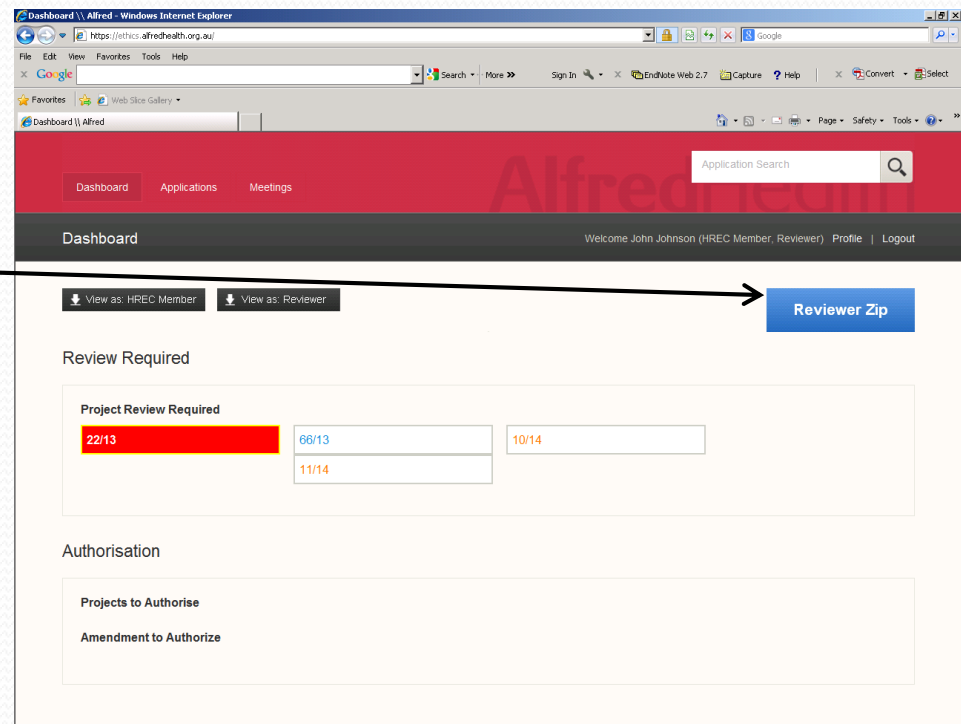
Dashboard (continued)

- On top of the page different ‘Menus’ are displayed:
 - Dashboard
 - Applications
 - Meetings
- Dashboard serves as your “home” screen.
- Clicking on ‘Application’ will display a search “engine” for applications. Search filters that can be applied are: A project’s status, category, researcher and administrator.
- The site displayed when clicking on the ‘Meeting’ menu will allow you to access meeting information as well as search for meetings in a particular time period.
- The easiest way to search for a particular project is to type the project number (e.g. 3/14) in the ‘Application Search’ field on the top right. The system will offer applications containing the typed numbers along with the project’s status and the Ethics Officer looking after the project.



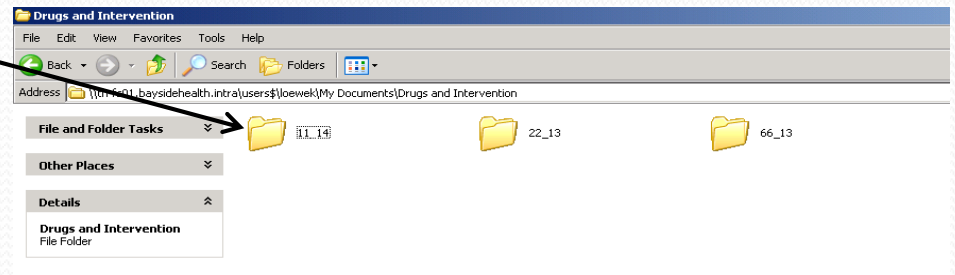
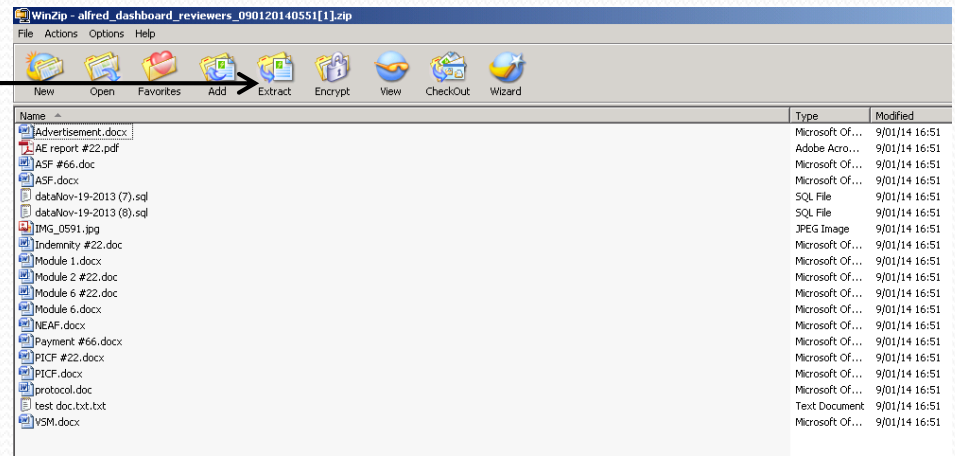
Reviewing: Accessing application documents

- The projects assigned to you for review will appear in boxes underneath 'Project Review Required' on your dashboard.
- To access the application documents via the dashboard, click on 'Reviewer Zip' (blue button in the right corner).
- Clicking on **Reviewer Zip** will open a box giving you the option to either open the files directly or to save them to a desired location on your device.
- Documents should appear separated into folders according to their project number. If this is not the case, i.e. all documents are displayed together, please see next page for problem solving.



Reviewing: Accessing application documents (continued I)

- If documents are not separated into folders (as shown on the right), click 'Extract' in top row in the zip folder, which would have opened after clicking on 'Reviewer zip'. This will open a box.
- Choose the location you wish to save the files in and click 'Extract'.
- The application documents have now been saved in your desired location separated into categories (D&I, H&SS and Low Risk) and grouped into folders according to their project number.



Reviewing: Accessing application documents (continued II)

Instructions for viewing marked-up (tracked changes) documents in Word 2007*

Click on the 'Review' tab. Look at the third box across called 'Tracking'. On the top right hand side of this box, see the option "Final Showing Markup". There is a drop-down menu here (click on the little down arrow) with 4 options:

- Final showing markup
- Final [this shows the 'clean' doc with all proposed changes included]
- Original showing markup
- Original [this shows the doc before *any* changes were made]

We recommend that you initially select 'Final showing markup'. If this is too hard to read (e.g. there are a large number of changes) or if you want to check what the final version looks like, you can view the clean final by selecting the 'Final' view.

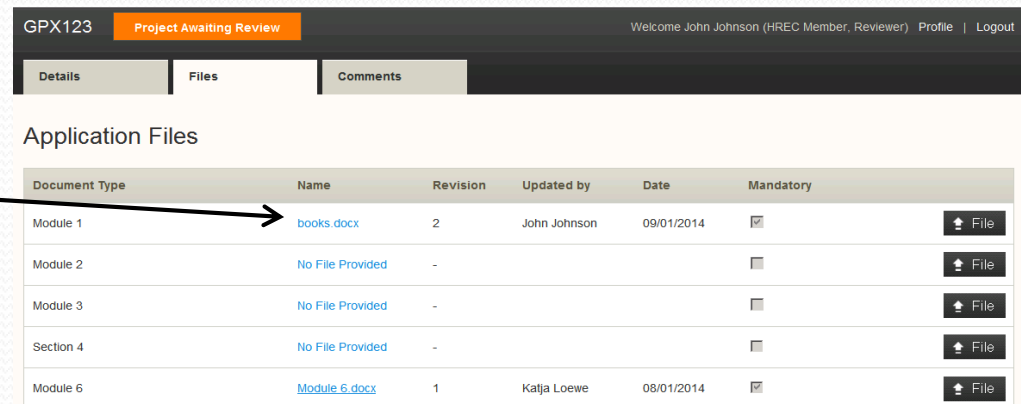
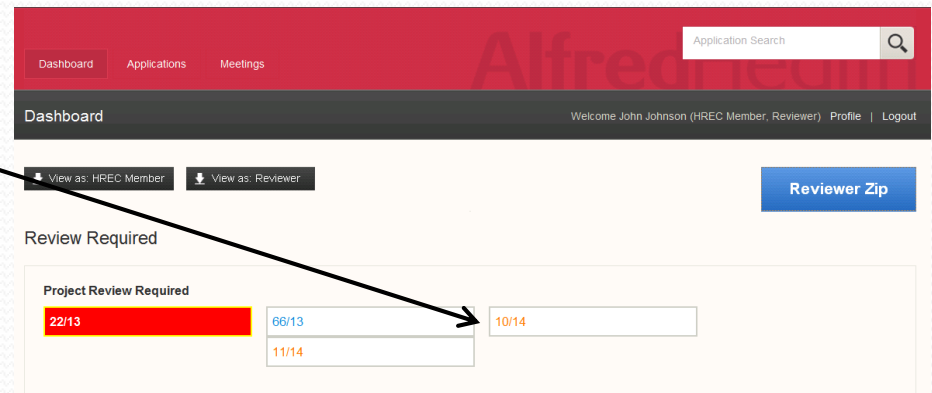
**These instructions are for Microsoft Office Word 2007. Users of older versions of Microsoft Word can find instructions on-line, e.g.:*

Microsoft Office Word 2003/Microsoft Word 2002: <http://office.microsoft.com/en-au/word-help/viewing-markup-in-word-HA001045131.aspx>



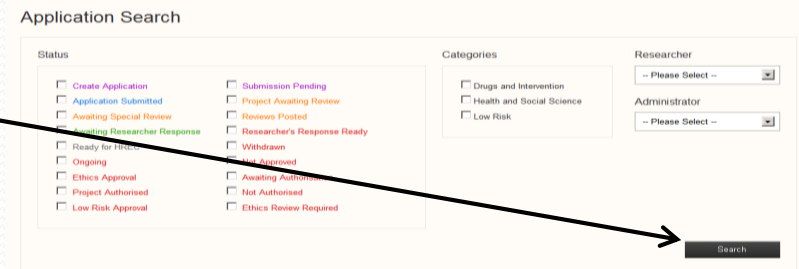
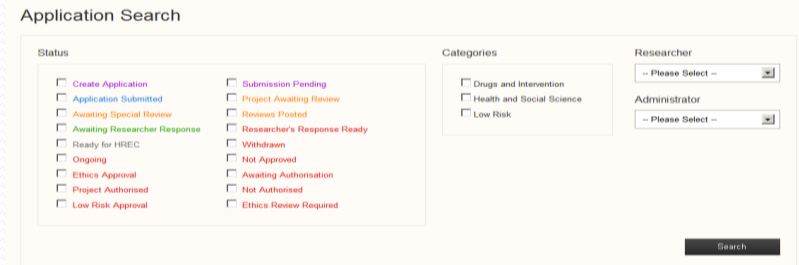
Reviewing: Alternative access of files/accessing single files online

- Clicking on the desired project number on your dashboard will take you to the project's 'Application container'.
- In the application container three tabs are displayed:
 - 'Details' offers project-specific information
 - 'Files' contains the application documents
 - 'Comments' is used to post your review.
- To access a single file in the 'Files' tab click on the blue file name of the document you wish to view.
This will open a box offering the choices to either save or open the document.



Reviewing: Accessing files of projects not assigned to you

- If known, type the project number in the 'Application Search' field (top box on right) and select the desired project number. This will take you to the project's 'Application container'. Go to the 'Files' tab to access relevant files.
- To view projects for consideration at the RRC or EC meeting please see the slides relating to '[Meeting: Viewing/accessing information for projects for discussion](#)'
- Alternatively the application search function can be used. Click on 'Application' (top of the page, in red coloured area). Search filters that can be applied are: A project's status, category, researcher and administrator.
- If no search filter has been applied, clicking on 'Search' will give you a list of all projects in the system.



Posting your review

- Your review can be posted via the 'Comments' tab in an individual project's container.
- Click on **+ New comment** and then choose the document to which the comment relates from the drop-down box.
Enter your comment and click **Save Comment**.
- Once saved a comment cannot be changed by you.
- Saving a comment deposits it into the system, but does not finalise the review (see next page). This will allow you to add further comments later.
- Comments can be exported to a PDF by clicking on the corresponding black button **Export to PDF** with the option to view or save the file.

Dashboard Applications Meetings

GPX123 Project Awaiting New Comment

Details Files

Comment Permitted contraception methods need to be clarified.

Related to 1 - Protocol Main

Application Comments

Protocol Main - (Revision 1)

Sample size calculation is missing. Please amend the protocol accordingly.

John Johnson - 09/01/2014

Cancel Save Comment

Finalise Review

Export to PDF

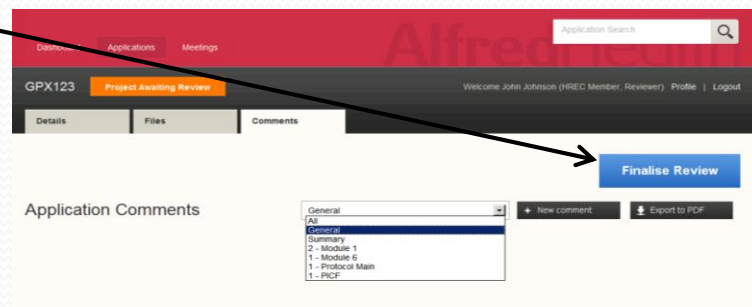
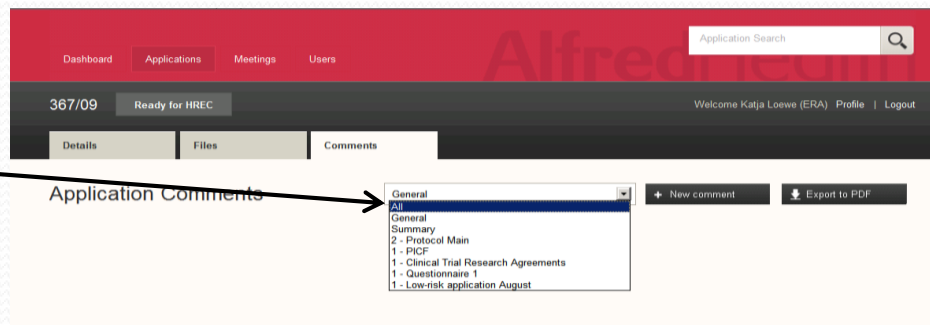
Posting your review (continued)

- Multiple comments can be made against the same document.
- To view all comments related to an application choose 'All' in the drop-down menu.

Alternatively comments against a specific file

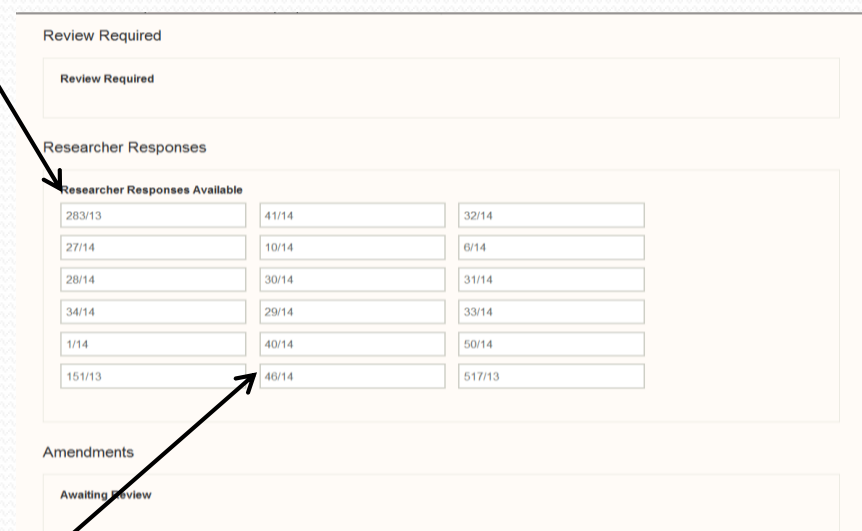
(e.g. protocol) can be viewed by selecting the document from the drop-down menu.

- Clicking on 'Finalise review' completes the review. After finalising additional comments cannot be made. The project will disappear from your dashboard. You can still access the projects' information and files by typing the project number in the 'Application Search' box (top right corner).
- You can respond to a comment by clicking 'Reply'. Please note that this option is limited to one reply per comment.
- Please note that only the Ethics & Research Governance staff and the other Committee members will be able to identify you as the reviewer, not the researchers.



Reviewing researchers' responses

- Projects with researchers' responses submitted either before or after the EC meeting will appear under 'Researcher Responses Available' on your dashboard. Only projects assigned to you will be shown. (To access projects not assigned to you please refer to the relevant [slide](#).)
- After the responsible Ethics Officer has made the researcher's response for a project available to you, it will appear on your dashboard. Please note that the alert for the EC agenda to be ready will only be sent when the agenda has been finalised, i.e. a researcher's response might appear on your dashboard before you receive an alert. You can be sure that all responses and the agenda will be available 6 pm the Thursday before the EC meeting.
- Click on the desired project number to get to the project's 'Application container'.



Review Required

Review Required

Researcher Responses

Researcher Responses Available

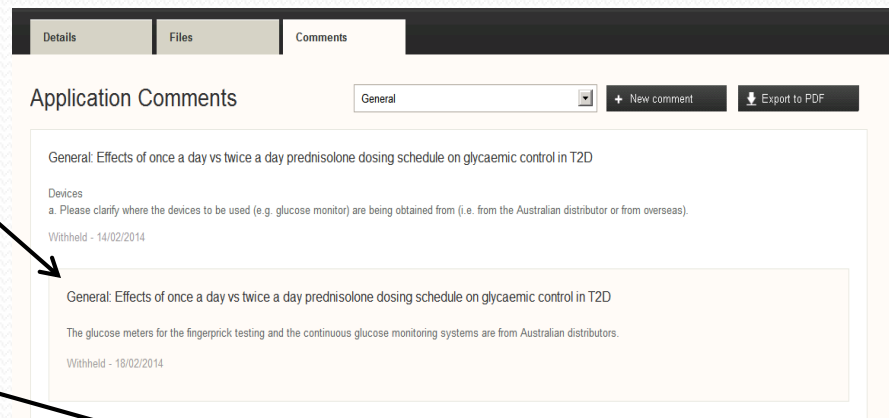
283/13	41/14	32/14
27/14	10/14	6/14
28/14	30/14	31/14
34/14	29/14	33/14
1/14	40/14	50/14
151/13	46/14	517/13

Amendments

Awaiting Review

Reviewing researchers' responses (continued)

- In the 'Comments' tab you can view the researchers' response to comments passed on to them.
- In the 'Files' tab new documents uploaded and revised documents submitted can be identified by their upload date (fifth column).
- When an amended document has been submitted, you can see the previous document versions by clicking on the revision number (third column). The item will expand and show previously submitted versions underneath. To retract click on the revision number again.
- Please review all new documents and revised documents relevant to you!



Details Files Comments

Application Comments

General

+ New comment Export to PDF

General: Effects of once a day vs twice a day prednisolone dosing schedule on glycaemic control in T2D

Devices

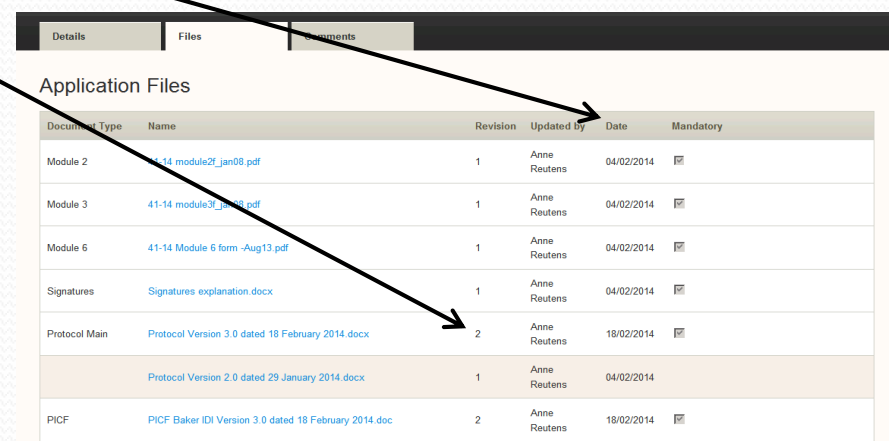
a. Please clarify where the devices to be used (e.g. glucose monitor) are being obtained from (i.e. from the Australian distributor or from overseas).

Withheld - 14/02/2014

General: Effects of once a day vs twice a day prednisolone dosing schedule on glycaemic control in T2D

The glucose meters for the fingerpick testing and the continuous glucose monitoring systems are from Australian distributors.

Withheld - 18/02/2014



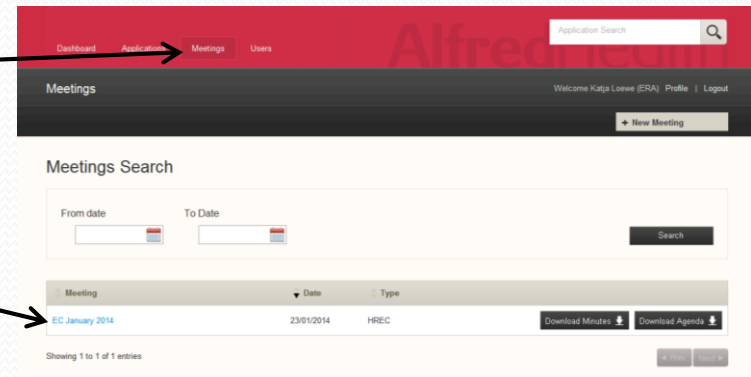
Details Files Comments

Application Files

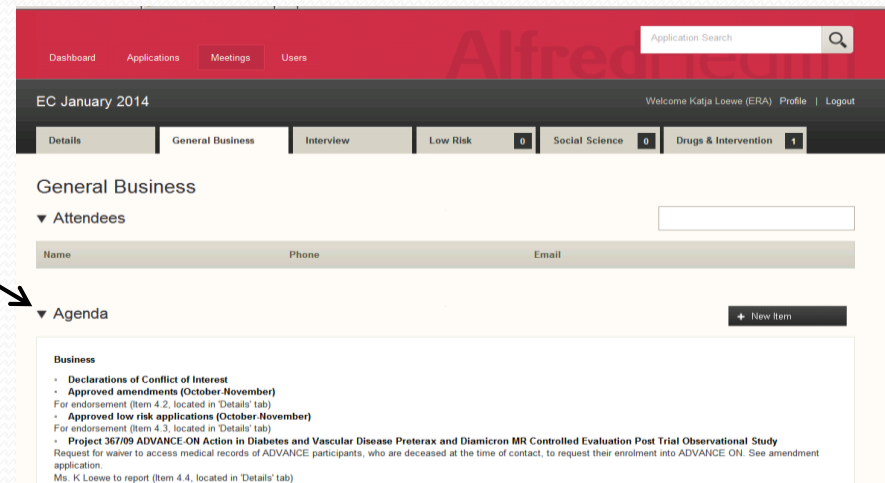
Document Type	Name	Revision	Updated by	Date	Mandatory
Module 2	41-14 module2f_jan08.pdf	1	Anne Reutens	04/02/2014	<input checked="" type="checkbox"/>
Module 3	41-14 module3f_jan08.pdf	1	Anne Reutens	04/02/2014	<input checked="" type="checkbox"/>
Module 6	41-14 Module 6 form -Aug13.pdf	1	Anne Reutens	04/02/2014	<input checked="" type="checkbox"/>
Signatures	Signatures explanation.docx	1	Anne Reutens	04/02/2014	<input checked="" type="checkbox"/>
Protocol Main	Protocol Version 3.0 dated 18 February 2014.docx	2	Anne Reutens	18/02/2014	<input checked="" type="checkbox"/>
	Protocol Version 2.0 dated 29 January 2014.docx	1	Anne Reutens	04/02/2014	<input checked="" type="checkbox"/>
PICF	PICF Baker IDI Version 3.0 dated 18 February 2014.doc	2	Anne Reutens	18/02/2014	<input checked="" type="checkbox"/>

Meeting: Viewing/accessing agenda items

- Go to the 'Meeting' menu on top of the page (in red coloured area).
- Clicking on the blue-highlighted meeting will take you to the 'Meeting Details' page.

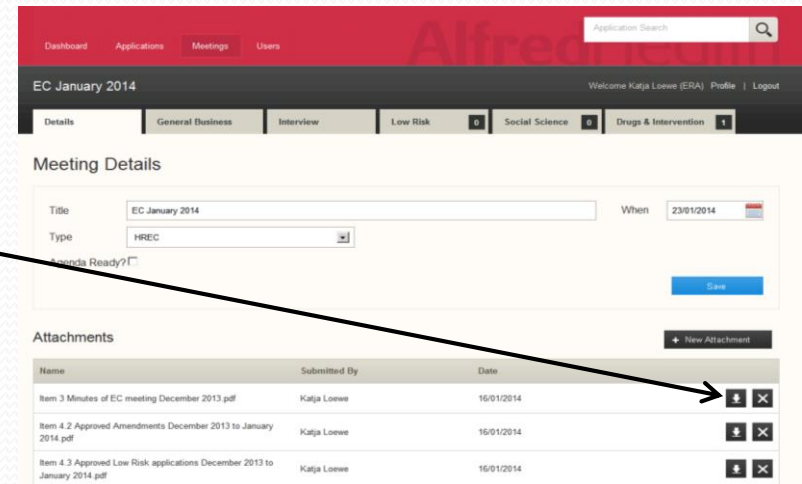


- In the 'General Business' tab agenda items will be listed. To view these please expand 'Agenda' by clicking on it.






Meeting: Viewing/accessing agenda items (continued)

- Documents relating to Business items (e.g. list of approved amendments, last month's EC meeting minutes) can be downloaded by clicking on the corresponding arrow for a particular item listed in the 'Details' tab.



The screenshot shows the Alfred system interface. At the top, there's a navigation bar with 'Dashboard', 'Applications', 'Meetings', and 'Users'. Below this, the page title is 'EC January 2014'. The main content area has tabs for 'Details', 'General Business', 'Interview', 'Low Risk', 'Social Science', and 'Drugs & Intervention'. The 'Details' tab is active, showing 'Meeting Details' with fields for Title ('EC January 2014'), Type ('HREC'), and When ('23/01/2014'). Below this is an 'Attachments' section with a table listing documents. A black arrow points from the text in the list to the download icon in the first attachment row.

Name	Submitted By	Date	Download
Item 3 Minutes of EC meeting December 2013.pdf	Katja Loeve	16/01/2014	
Item 4.2 Approved Amendments December 2013 to January 2014.pdf	Katja Loeve	16/01/2014	
Item 4.3 Approved Low Risk applications December 2013 to January 2014.pdf	Katja Loeve	16/01/2014	

Meeting: Viewing/accessing information for projects for discussion

- H&SS projects are listed in the 'Social Science' tab, D&I applications for discussion at the meeting are displayed in the 'Drugs & Intervention' tab.
 - To access files and view comments relating to a project please click the "button" next to the project's short title.
 - 'Files', 'Comments' and 'Minutes' will appear underneath the table. These can be expanded and retracted.
 - When expanding files, documents can be viewed/downloaded by clicking on the download arrow.
- Please note that only the latest version of a document can be downloaded from here ('Meeting' menu). To access previous versions of a document, please refer to the slide '[Reviewing researchers' responses \(continued\)](#)'.
- Comments and replies made by the researchers can be viewed by expanding 'Comments'. To make a comment, please refer to '[Posting your review](#)'.

Application	Project#	Status	Reviewers
BD608+best supportive care vs placebo+best supportive care in pre-treated advanced colorectal carcinoma	283/13	Ready for HREC	Annette Bennet, Chris Booth, Kate Cherry, Marina Skiba
Effects of once a day vs twice a day prednisolone dosing schedule on glycaemic control in T2D	41/14	Ready for HREC	Elizabeth Burns, Henry Krum, Nicola Taylor, James Shaw
Accuracy Of Intensivist Performed DVT Ultrasound Screening In Trauma ICU Patients	10/14	Ready for HREC	Annette Bennet, David Kaye, Arthur Rallis, Flavia Cicuttini
Phase IV study to investigate efficacy + safety of ranibizumab "inject&extend" using an intensive retinal fluid retreatment regimen compared to a relaxed retinal fluid retreatment regimen in AMD pts	29/14	Ready for HREC	Chris Booth, Kate Cherry, Nicola Taylor, Anne Mak
The Australian Destination Therapy Mechanical Circulatory Support Study	1/14	Ready for HREC	Elizabeth Burns, Peter Gallagher, Henry Krum, James Shaw

BD608+best supportive care vs placebo+best supportive care in pre-treated advanced colorectal carcinoma

Files

Document Type	Name	Revisions	Updated By	Date
ASF	Alfred specific form-Feb19 2014.doc	2	Nikki Cross	19/02/2014
Signatures	signature pages.pdf	1	Nikki Cross	05/02/2014
Protocol Main	CO23_Protocol_Amend1-2013JUN12.pdf	1	Nikki Cross	03/02/2014
Budget	BUDGET.doc	1	Nikki Cross	05/02/2014
Investigator's Brochure	ib_bdi20 edition 1 2013mar/21 ib.pdf	1	Nikki Cross	03/02/2014