Government of **Western Australia**
Department of **Health**

Research Governance Service (RGS)

Ethics Executive Officer (EEO) User Guide

Version 3.0

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1. My Dashboard

My Dashboard allows you to see project and their current status. There are three Dashboards, one for Researchers, Research Governance Officers (RGOs) and Ethics Executive Officers (EEOs)

1.1 My Dashboards vs. My Projects

My Projects only list the all the projects where you are a member. It provides minimal information about each project and functions as a quick way to open a project workspace.

My Dashboard is interactive and contains all the projects where you are an active member. If you are involved in a number of projects it allows you to easily filter or sort the projects in the order that you want.

1.2 Sorting My Dashboards

You can sort on any column by clicking on the column heading and it will sort in ascending order. Clicking it again will sort it in descending order.

The columns are

- Phase – this is the phase the project is in either Application or Monitoring.
- PRN – the is the Project Reference Number
- Title – the title of the project
- CPI - the Coordinating Principal Investigator
- Project Status – this is where the project is at the time that you are looking at it.
- Risk – this is the risk that has been assigned to the project by the reviewing HREC.

1.3 Filtering My Dashboards

The filter option is accessed by clicking on the filter icon on the right of the column headings.

When you have opened the filter you will see a search under each column heading. Two of these (Phase and Project Status) have drop down menus that you can use to filter the projects. The other columns allow you to enter a number or word that you can filter on.

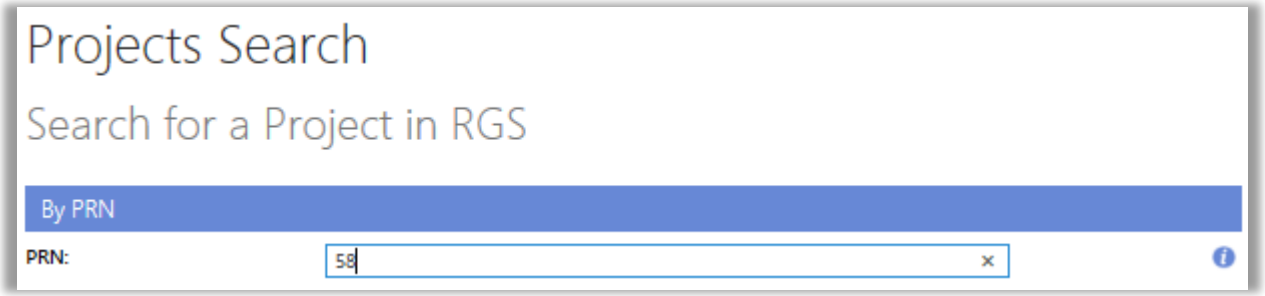
You can filter on just one column or multiple. As you go from one column to the next the filter will narrow your results. You can go to the project workspace by clicking on the PRN.

2. Assisting Researcher before submission

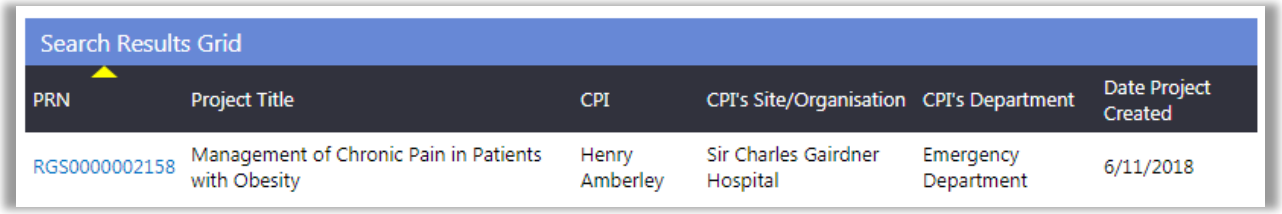
You can access a project once the HREC has been selected in the Project Details and section 1 has been authorised. Until the project has been submitted you will have to access it using Project Search.

Project search is in the left hand menu when you are logged into RGS

Enter the PRN, you don't need to enter the preceding zeros and click search.



The search grid will show all projects that meet the number criteria. Click on the PRN to access the project workspace.



3. Manage the Committee Members

Committee members are managed through the Manage Committee screen. Ethics Executive Officers (EEO) have access to the committees that are assigned to their Ethics Office. If you don't have Administration in your left hand menu then you need to contact an RGS Administrator to ensure that you have the EEO role assigned to you and that you have been added to the correct Ethics Office.

3.1 Add a Committee Member

Adding a committee member to a committee is done through the Administration menu. This is located on the left hand side of the Home screen. Click on 'Administration' and then 'Manage Committees'. The 'Edit Committee' button will only be active on committees that are assigned to your Ethics Office. Select the committee, and click 'Edit Committee'.

You can go to the 'Members' tab of the committee and add the members you want. All users who have the role of Committee Member will be in the list. Refer to Help Wiki: Roles in RGS for the descriptions of the roles in RGS.

Click 'Add Member'. Under the Find Member you can either add their name if you know it and press the check names icon or alternatively you can click the browse button and search from the list of available members.

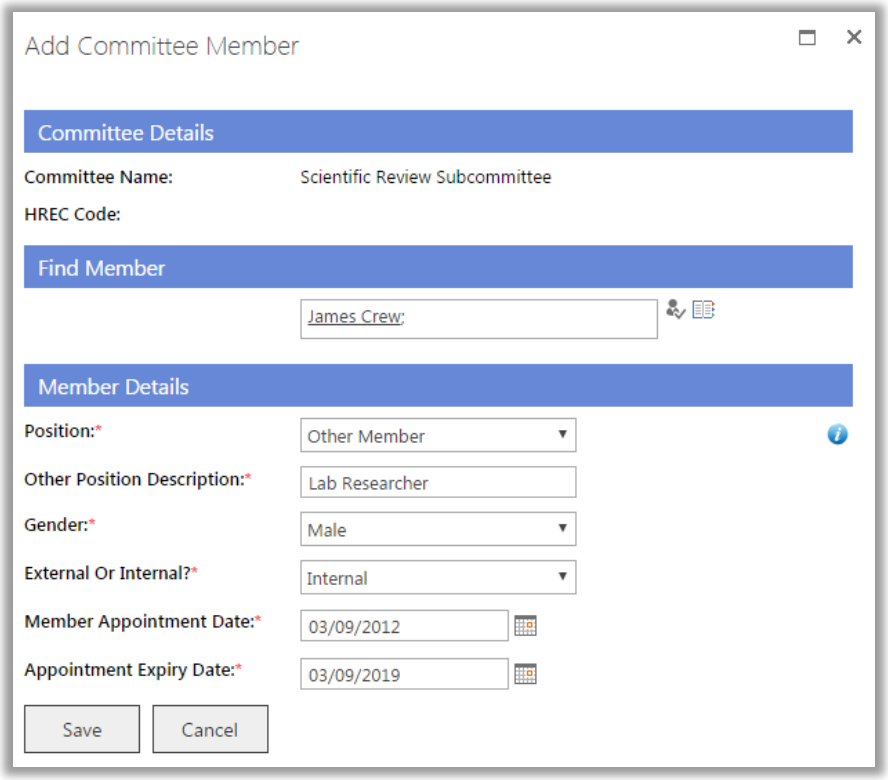
Once you have selected the member, enter the Member Details. These are mandatory fields must be completed before the information can be saved.

The position each member will hold on the committee is mandatory. The current positions in RGS are the positions in the National Statement Section 5.

- **Position** – is the position the person holds on the Committee. There can be multiple people holding the same position on a committee.
- **Gender** – is the person's gender.
- **External or Internal** – if the person is employed by the sponsoring institution they are internal otherwise they are external.
- **Member Appointment Date** – this is the date the person was first appointed to the Committee.

- **Appointment Expiry Date** – this is the date the person's current appointment is due to expire.

If the position is not in the list you can use the position of 'Other' and an additional field will be added so that you can enter a description.

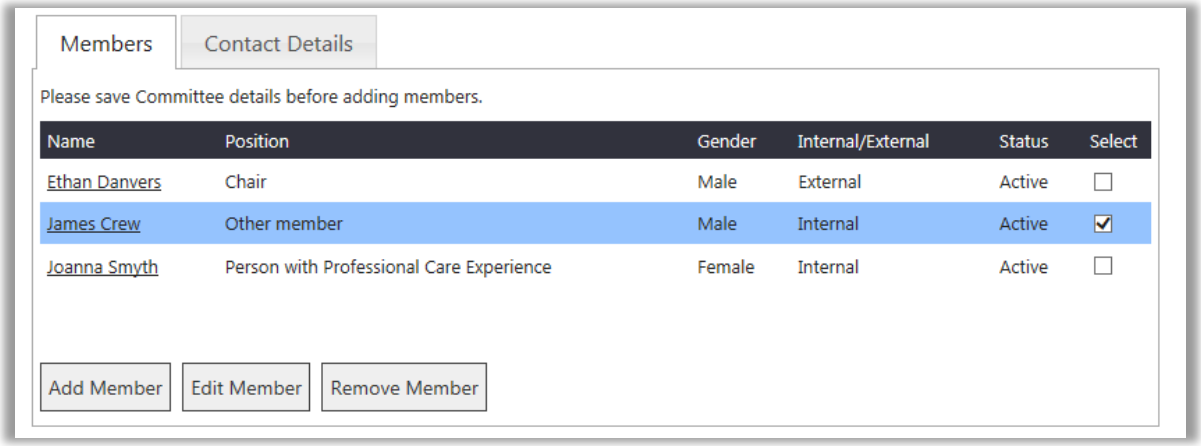


When all the information is completed click 'Save'. You can then add another member.

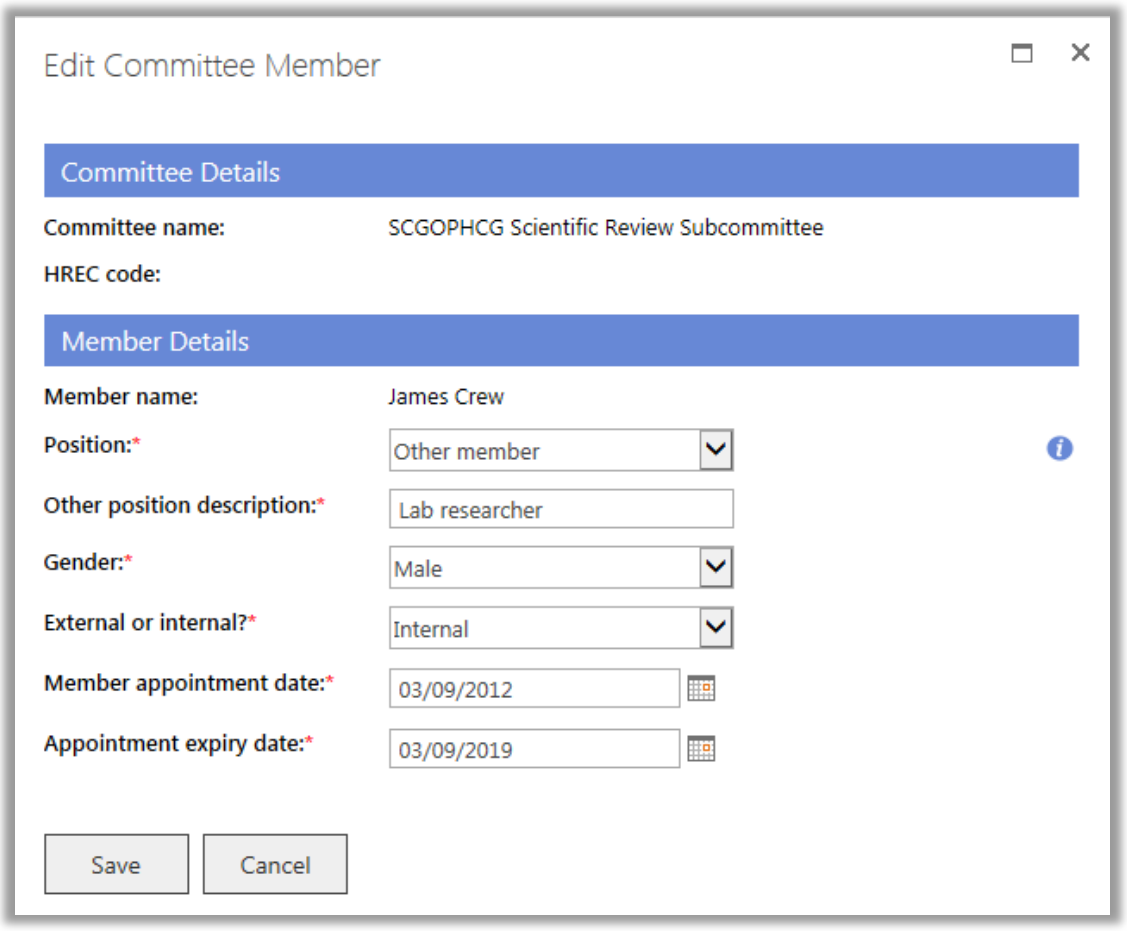
3.2 Edit a Committee Member's Details

If a committee member's details have to be updated, such as a change in position, or the term as a committee member, these must be updated in RGS. To edit a committee member's details click on Administration and then Manage Committees. Select the person's committee and click 'Edit Committee'.

On the members tab select the committee member. The 'Edit Member' and 'Remove Member' buttons become active. Click 'Edit Member'.

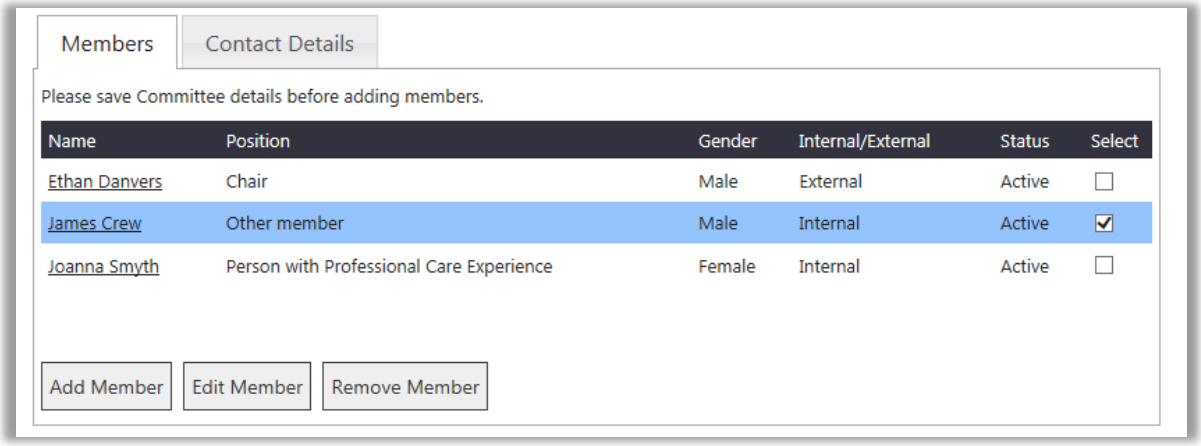


The Edit Committee Member screen launches. Amend the person's details and then click 'Save'. The screen will close and you will go back to the previous screen. Remember to also click 'Save' on this screen to save the information for the committee.

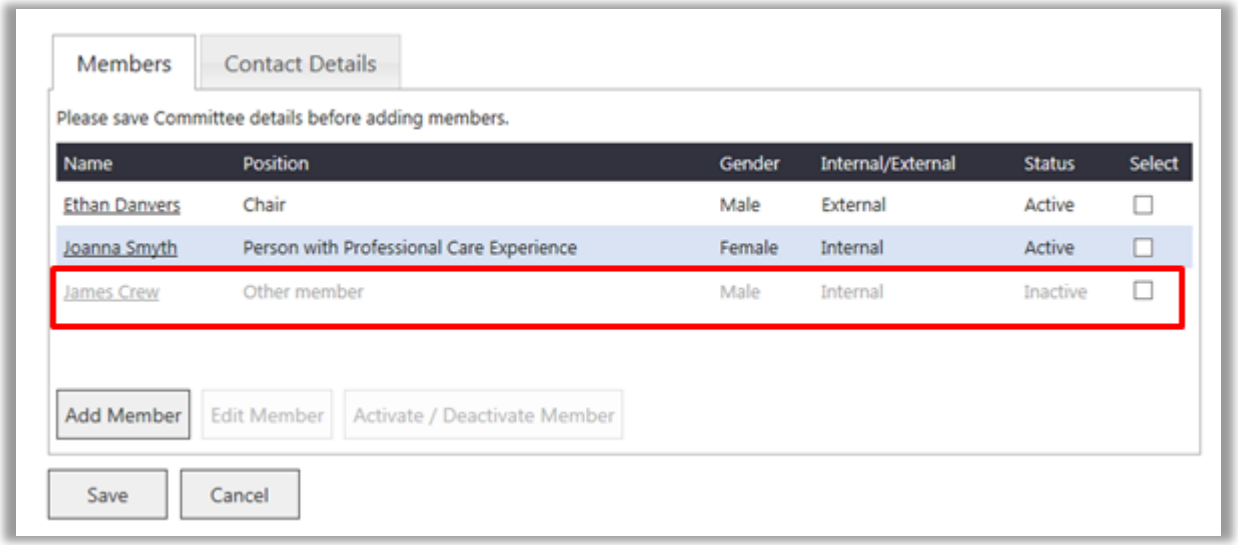


3.3 Remove a Committee Member

To remove a committee member click on Administration and then Manage Committees. Select the committee that you want to remove the committee member from and click 'Edit Committee'.



On the Members tab select the committee member you are going to remove. The 'Edit Member' and 'Remove Member' buttons become active. Click 'Remove Member'.



The removed committee member will go to the bottom of the screen, their status is 'Inactive' and they are greyed out. They can no longer be added to a meeting. All the meeting information related to the member is retained in the minutes and available for reporting.

Remember to click 'Save' at the bottom of the Committee page to save all changes.

3.4 Activate a Committee Member

If the person has been assigned to a committee previously and has been removed as a member you can reactivate them as a member of the committee. Click on Administration and then Manage Committees. Select the committee that you want to add the person to and click 'Edit Committee'.

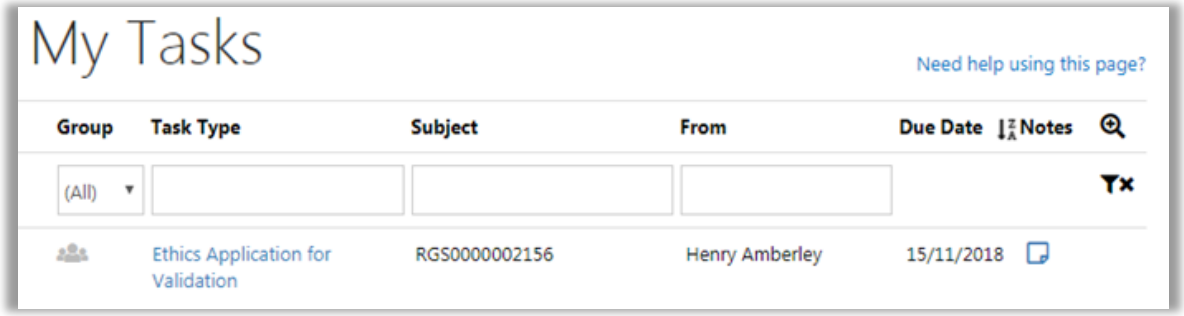
The committee member will be at the bottom of the list and greyed out, select them and click 'Activate Member'. The member's status will change to active. You can then go and update the member's details through 'Edit Member'.

4. Validate an Application

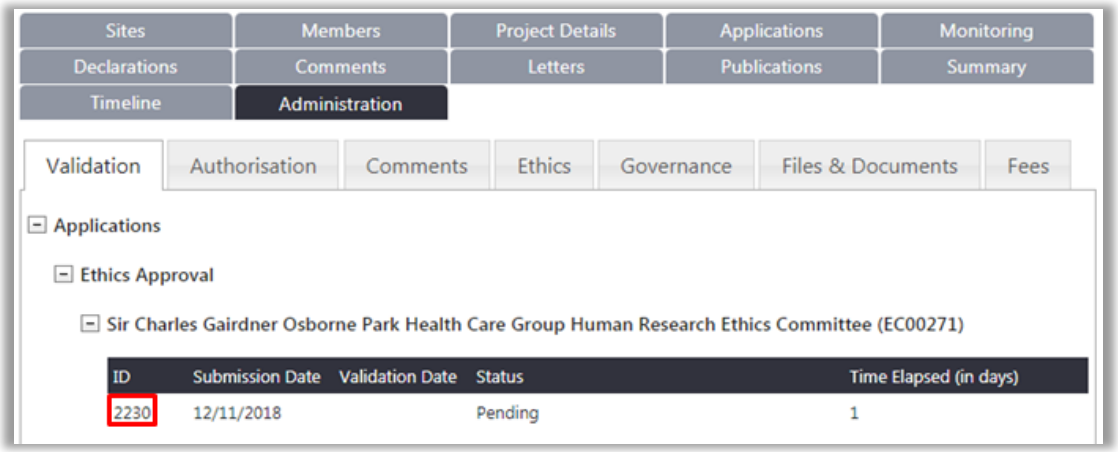
Note that a project cannot submit another form or document within the same category (e.g. Ethics Approval) until the validation of any previous submission in the same category has been completed. Hence, it would be a good practice to action pending Validations in a timely manner.

The My Tasks menu link is located in the left-hand menu visible when you are logged into RGS. When a submission is made to an ethics committee a task will appear in My Tasks for all the EEOs in the Ethics Office of the related HREC.

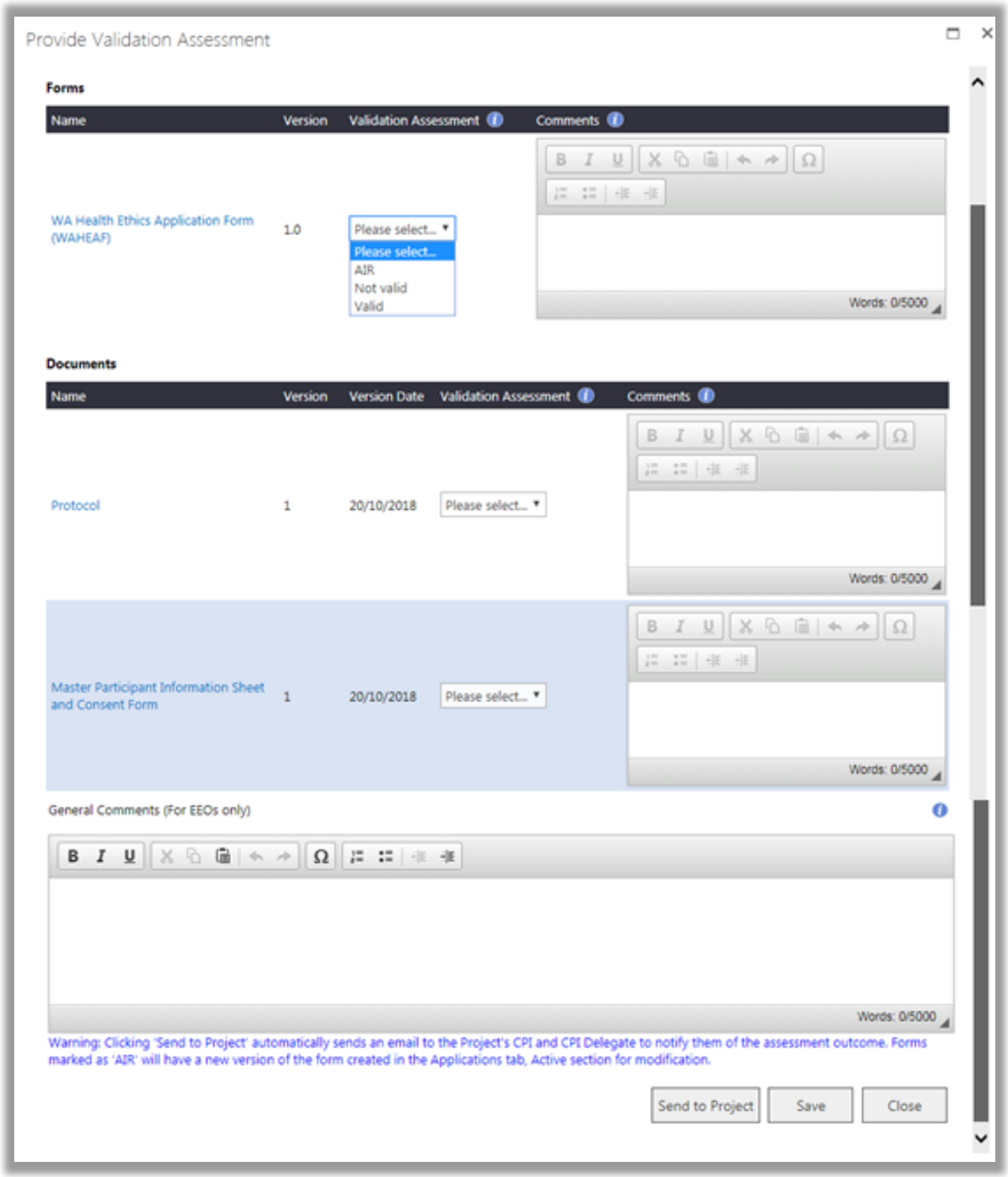
To find out more information about tasks go to the Help Wiki 'All about Tasks' .
When you 'Action' the task you will be taken to the project workspace's Validation tab which is



in the Administration tab. The Administration tab is only visible to EEOs, RGOs and Hospital Administrators who are invited to authorise research at a site. To commence the validation of the submission press the ID number (highlighted in red below).



The Provide Validation Assessment screen will appear. This screen will allow you to view and assess each form and document submitted.



Your options for assessment are:

Valid

If on reviewing the submission a form or document contains sufficient information the form or document can be marked as valid. Once it is marked as valid it can be added to an agenda.

Additional Information Required (AIR)

If on reviewing the submission a form or document contains insufficient or incorrect information you can request the CPI provide the information by assigning the form or document an AIR status. You will need to also provide information in the comment box next to the validation assessment that the CPI can read and address this when resubmitting the form/document.

Not Valid

If on reviewing a document it is found to not be related or not relevant to the project, you can mark the document as 'Not Valid' and give your reasons in the comments section against the document.

EEO Comments

The screen also captures any EEO comments. However, these are not mandatory.

The 'General Comments (For EEOs only)' can be handy. It can give you or another EEO in your office information on the validation review that you don't necessarily want to feedback to the CPI but you need other people working in your Ethics Office to know. This information stays in the Provide Validation Assessment screen; it doesn't appear of the Validation Assessment screen the is viewed by the project members.

4.1 Validation Outcome

If either the WAHEAF or WASM is given the validation status of AIR a new version of the form is created in the Forms & Documents tab under Ethics Approval - Active - Forms section. If they edit the new version of form the CPI and PI(s) will have to re-authorise it before submitting it.

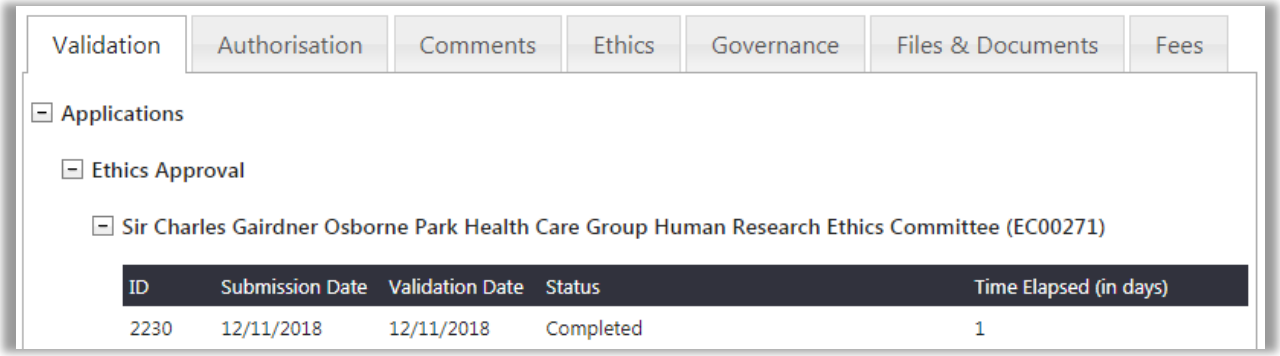
If a document is given the assessment of 'AIR' then a placeholder is created for the document. The CPI can then provide the additional information and submit a new version of document. If the review assessment is 'Not Valid' no place holder is created so the document cannot be resubmitted.

When all the forms and documents have a review assessment against them the 'Send to Project' button becomes available, You can click 'Save' which will save the validation you have currently completed and allow you to come back to it later. If you have completed your validation and added all the comments you want to feedback to the CPI you can click 'Send to Project'. This will send an email to the CPI informing them that the application has been through the validation process and what the outcome was.

Click 'Send to Project' to complete the Validation.

4.2 Resubmission for Validation

When the CPI resubmits the form and/or document you will once again receive a group task. When you take this task the Validation tab will show the completed validation as well as the new submission with the status or pending. You can then go through the process of validating the new submission.

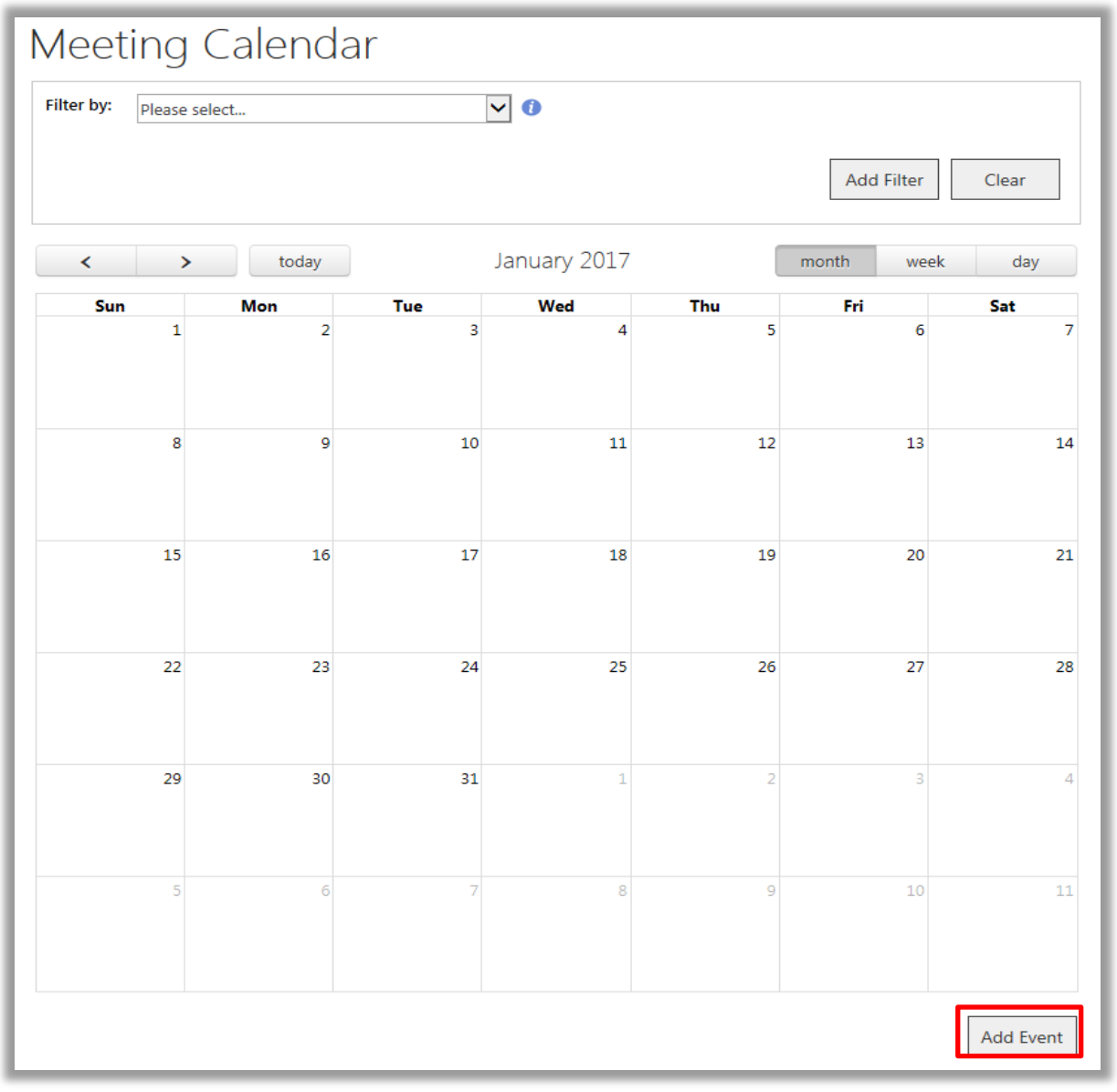


You can look at a completed validation by clicking on the new validation ID.

5. Maintain the Meeting Calendar

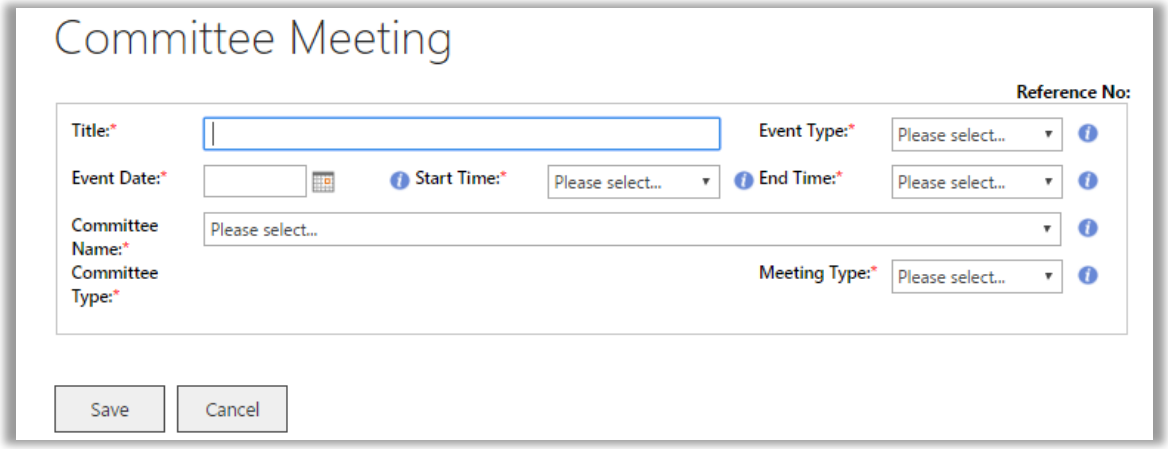
All application closing dates and meetings are created through the calendar. As an EEO you have the right to create these in the calendar for the committees associated with your Ethics Office. All application closing dates (ACD) and scheduled meetings are published on the calendar and can be seen by the public. Ad hoc meetings are also created through the calendar but they are not seen on the public view of the calendar.

Go to the calendar you should see the button 'Add Event'.



5.1 Create Application Closing Dates (ACD)

The ACD has to be created before any meeting dates associated with it. Click the 'Add Event' button and the screen below will appear.



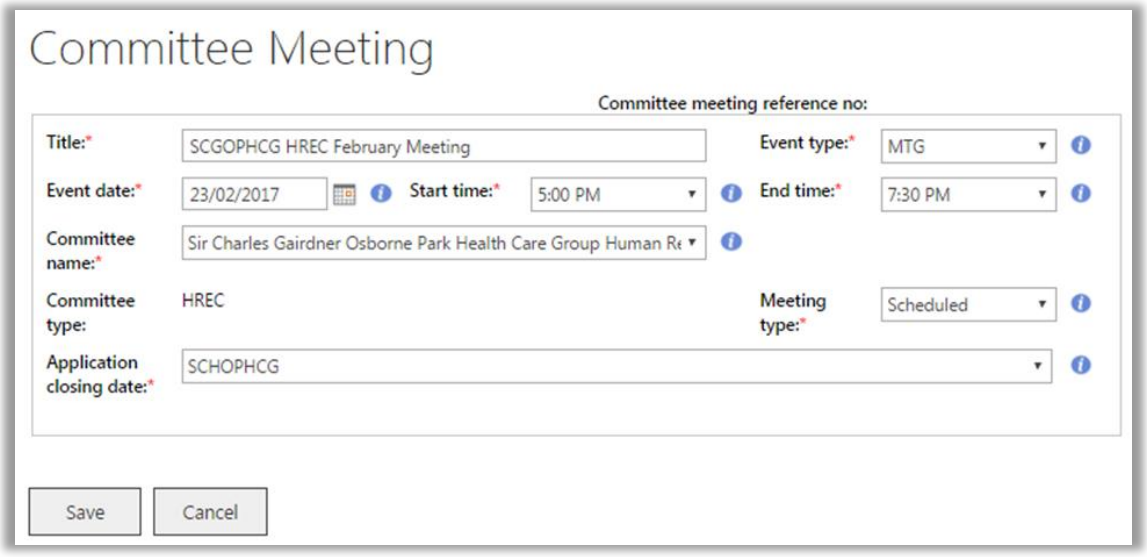
There are a series of mandatory fields that have to be completed to allow the ACD to be added to the calendar:

- **Title** – this should have the HREC name, the month of the meeting and that it is the deadline for submissions for that Committee (e.g. CAHS HREC October Meeting application closing date or submission closing date).
- **Event Type** – to create this type of event, select 'ACD'.
- **Event Date** – enter the date when the last submissions will be accepted for the meeting.
- **Start Time** – this is no longer editable.
- **End Time** – enter the time the last submission will be accepted for the meeting.
- **Committee Name** – the drop down should only show the committees the Ethics Office is associated with. Select the HREC the ACD is associated with.
- **Meeting Type** – this has disappeared as there is no meeting type associated with this ACD.

Once all the fields have been completed click 'Save'.

5.2 Create scheduled meetings

A scheduled meeting is a meeting that has been planned in advance, and will be shown to the public (i.e., even users who are not logged on to RGS). The meetings for a year can be added as soon as the Committee has agreed to them. Everything with a red asterisk (*) is a mandatory field.



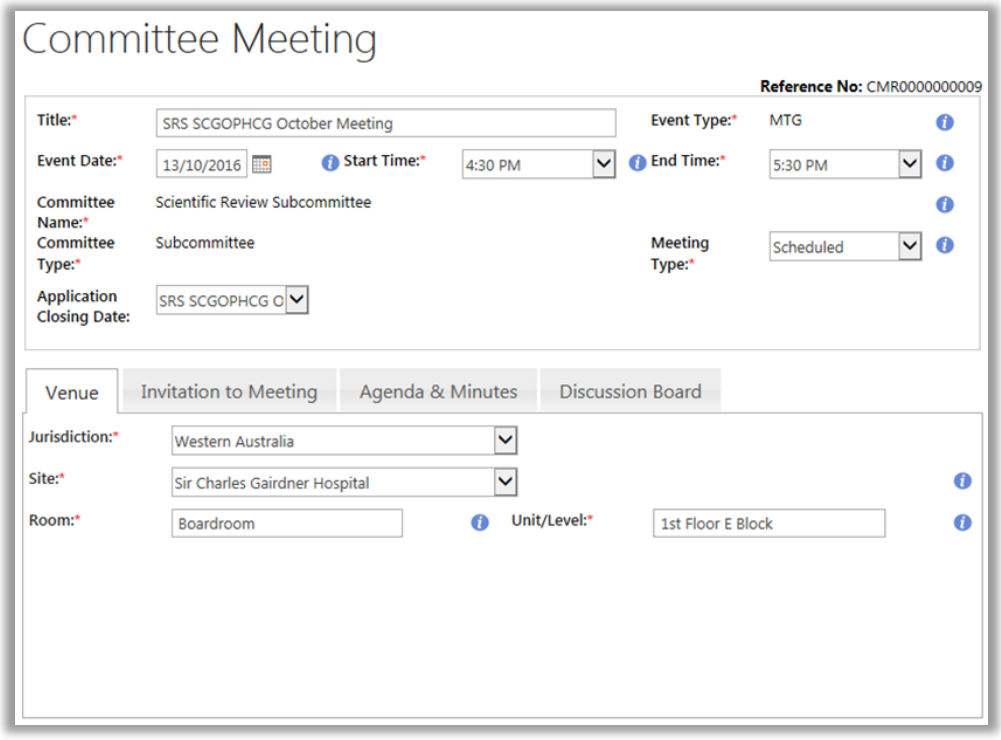
The mandatory fields that must be completed to allow the meeting to be added to the calendar are:

- **Title** – this should have the Committee name and the month of the meeting (e.g. SCGOPHCG HREC October Meeting).
- **Event Type** –select MTG.
- **Event Date** – this is date of the meeting.
- **Start Time** – this is the expected start time of the meeting. The actual start time can be entered into the agenda/minutes.
- **End Time** – this is the expected end time of the meeting. The actual end time can be entered into the agenda/minutes.
- **Committee Name** – the drop down should only show the committees that the Ethics Office is associated with. Select the appropriate committee.
- **Meeting Type** – for meetings within the agreed yearly meeting cycle select 'Scheduled' for HREC or subcommittee meetings. If a meeting is in addition to the meeting cycle, select 'Ad hoc'. For alternative review meetings refer to ad hoc meetings below.
- **Application Closing Date** - for scheduled meetings you will be able to choose from the ACDs you have previously created. If the meeting you are creating is for a subcommittee of the HREC you can use the same application closing date (if applicable) as the HREC.

Everything with a red asterisk (*) is a mandatory field, when all the information in the mandatory fields has been entered click 'Save'.

Once you have saved the meeting, the screen will expand to include a series of tabs associated with the meeting. These tabs are common to all meetings that are created, they are:

- **Venue** – this is where the meeting will take place.
- **Invitation to Meeting** – this tab is where you can invite committee members to the meeting and select who attended.
- **Agenda and Minutes** – this tab holds the agenda prior to the meeting and expands to include the minutes of the meeting.
- **Discussion Board** – this tab is available to committee members for discussion prior to the meeting.

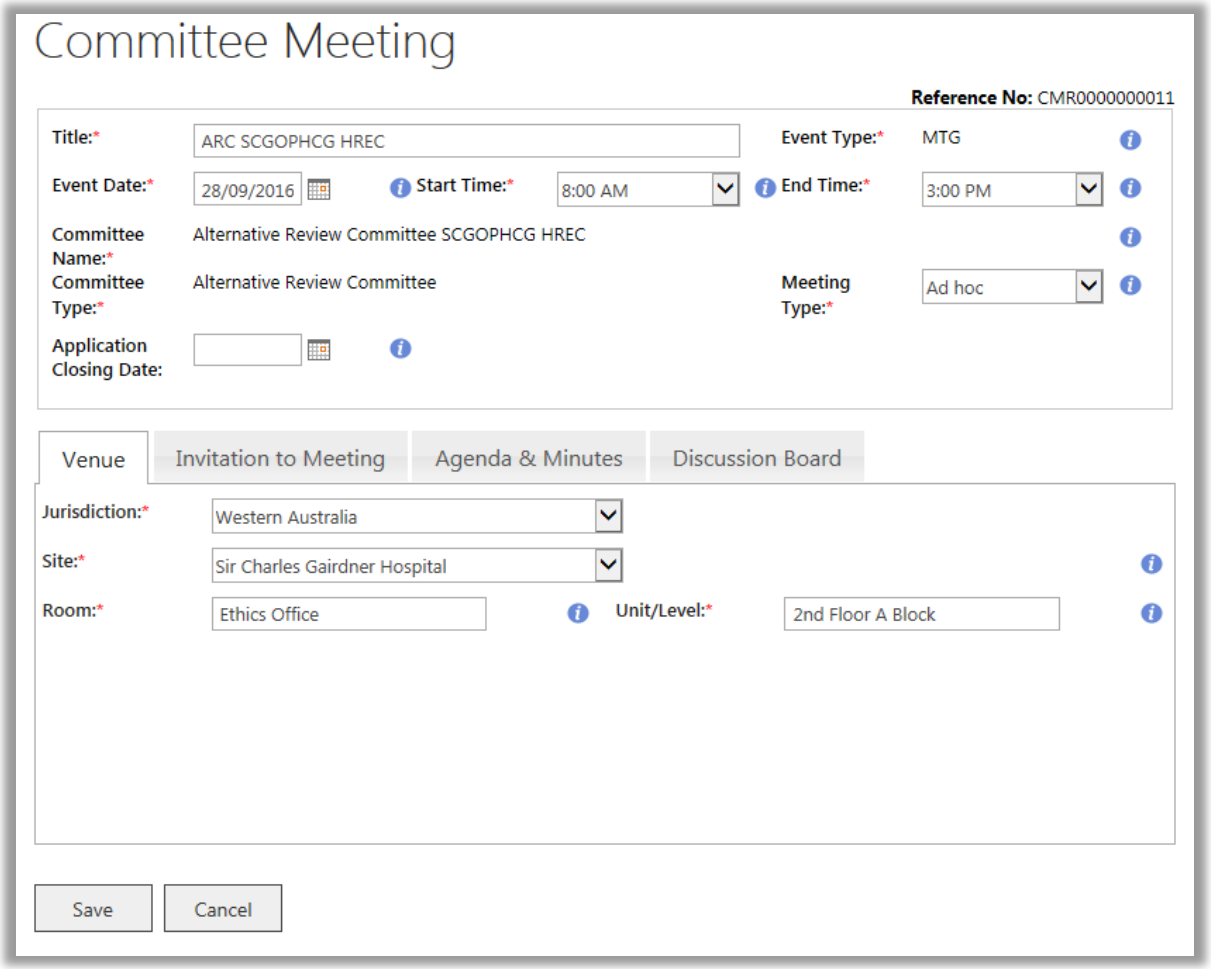


5.3 Create ad hoc meetings

An ad hoc meeting is a meeting that is not part of the normal meeting cycle for a committee or is a meeting for projects utilising Alternative Review. They are also not visible on the public view of the calendar, though any member of that committee invited to the meeting will be able to see them in their calendar.

The Alternative Review Committee meetings are the method used to review a project (e.g. low risk) outside of the normal meeting schedule. This should only be used if it has been agreed to by the HREC. This review type allows for the project to be reviewed and approved out of session, and added to the HREC agenda as an 'Item Reviewed Out of Session' later on.

An ad hoc meeting for a HREC or its subcommittee can be used to review projects out of session, that is outside of the normal meeting cycle, once again it should only be used if it has been agreed to by the HREC. **A subcommittee cannot use Alternative Review for reviewing out of session. The subcommittee can use an ad hoc meeting to review a project out of session.**



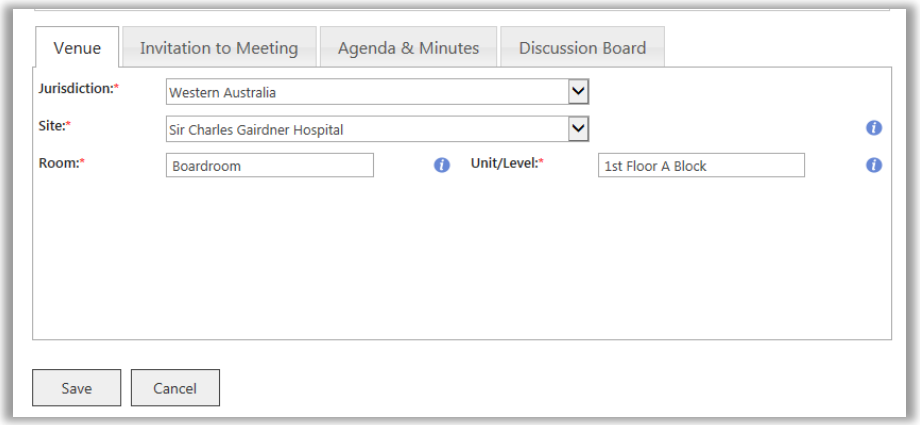
Similar to a scheduled meeting, once you have save the meeting the four tabs for the meeting will appear below the meeting details.

Click 'Save' to save all changes. To navigate away from the event screen click on Meeting Calendar at the top of the screen.

5.4 Adding the venue details

The venue details can be added when the meeting is created and/or updated at any time up to the day of the meeting. All mandatory fields have a red asterisk (*) next to them. Click 'Save' to save the changes made or 'Cancel' to discard them.

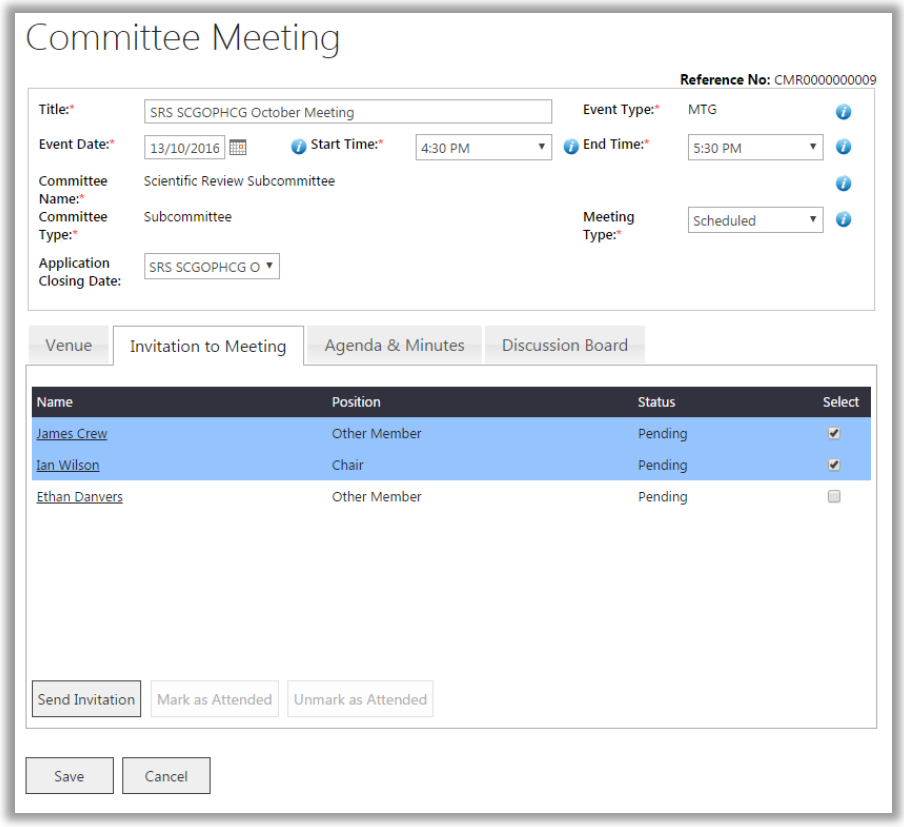
To update the venue later go to the calendar, select the meeting you want to update. The 'Venue' tab is the first tab and is the default tab visible when you open the meeting through the calendar. Enter all the changes and click 'Save'.



5.5 Invite a committee member to a meeting

Committee members can be invited to a meeting at any time up to and including the day of the meeting. To add a member to a meeting they must first be a member of the Committee. Refer to the instructions on manage committee members for the steps.

Through the calendar select the meeting you want to invite the member to. Go to 'Invitation to Meeting' tab.



Once you have selected the member, the ‘Send Invitation’ button will become active. Click ‘Send Invitation’ and the member will get an email with a link to the meeting. They can use this to access the agenda.

Each invited member will also have a task appear under their My Task section of Tasks which will also provide a link to the meeting. Once the member has been invited they can also access the meeting through the calendar. You can go back and invite other members at any time up to and including the day of the meeting.

Once the meeting time has passed you can no longer invite anyone to the meeting. You can mark them as attending by selecting the member and clicking ‘Mark as Attended’. Further information is located at Mark committee members’ attendance.

5.6 The discussion board

The discussion board is the last tab on the meeting. This can be used by committee members to discuss any item in the agenda prior to the meeting. It is very similar to a chat forum in that each discussion is kept together. Members should be made aware that any discussion created is visible to all committee members. Further information on the discussion board can be found on the Help Wiki: Contribute to a discussion board

5.7 Update the meeting details

Any meeting that has been created by you or another EEO in your office can be updated if needed. Go to the calendar and click on the meeting. The agenda will open and you can then edit the details of the information related to the meeting. This can only be done up to the start time of the meeting.

If you change the date and/or time after you have invited your members their status will change from invited to pending. You will then need to invite them again so that they receive the information that the date and time have changed.

Remember to click 'Save' at the bottom of the agenda page to save any changes that you have made.

6. Manage a meeting agenda

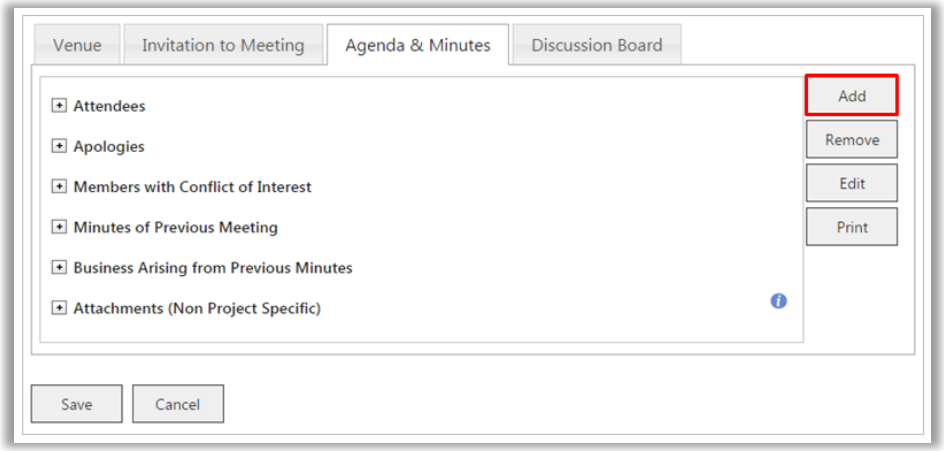
Each agenda has a number of basic categories that appear when the meeting is created. The following agenda items are default items and cannot be removed:

- Attendees
- Apologies
- Members with Conflict of Interest
- Minutes of Previous Meeting
- Business Arising from Previous Minutes.

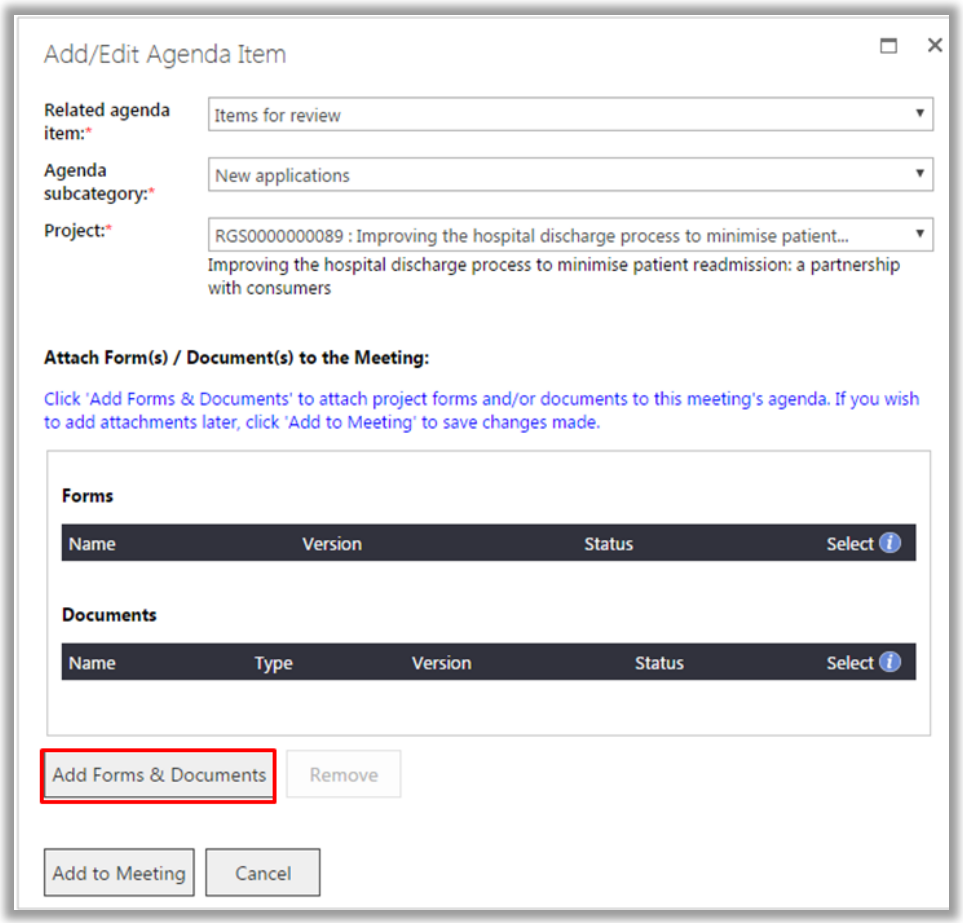
Additional sections of the agenda are created when items are assigned to the section such as when a research project is added to ‘Items for Review’. Agenda items can be added to a meeting any time, up to the time of the meeting.

6.1 Add a project from the calendar

Through the calendar, select the meeting you want to add the project to. Go to 'Agenda & Minutes' tab, and click 'Add'.

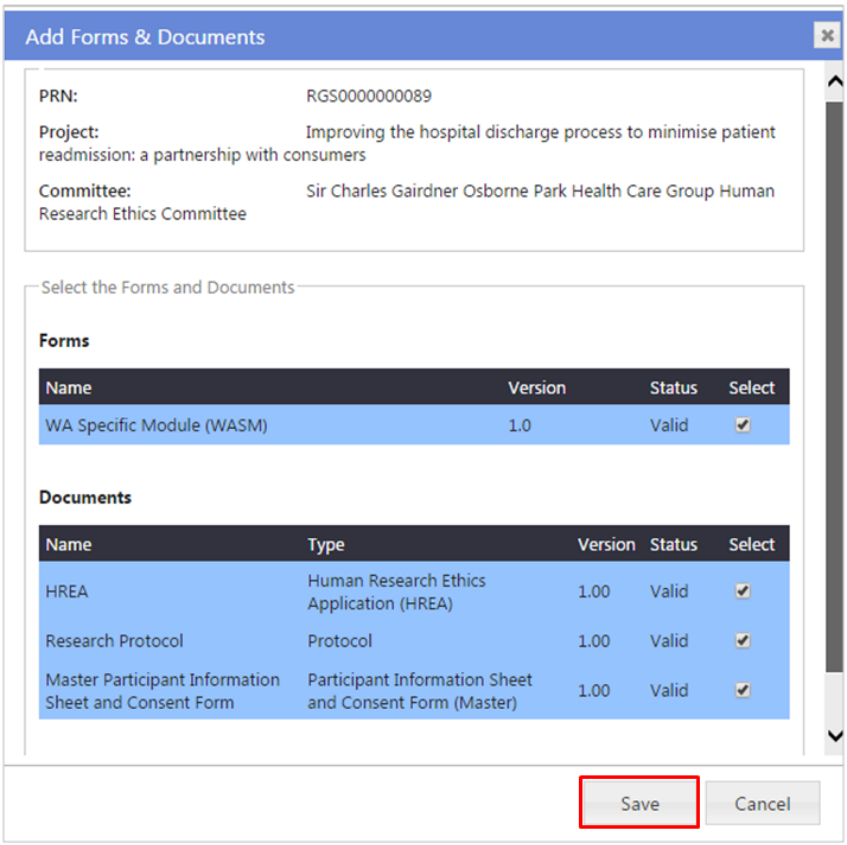


The 'Add/Edit Agenda Item' screen will be shown. Select the related agenda item and the agenda subcategory. For project that are to be reviewed select 'Items for Review', and then 'New applications'. You can add the forms and/or documents to be included in the agenda by clicking 'Add Forms & Documents'.

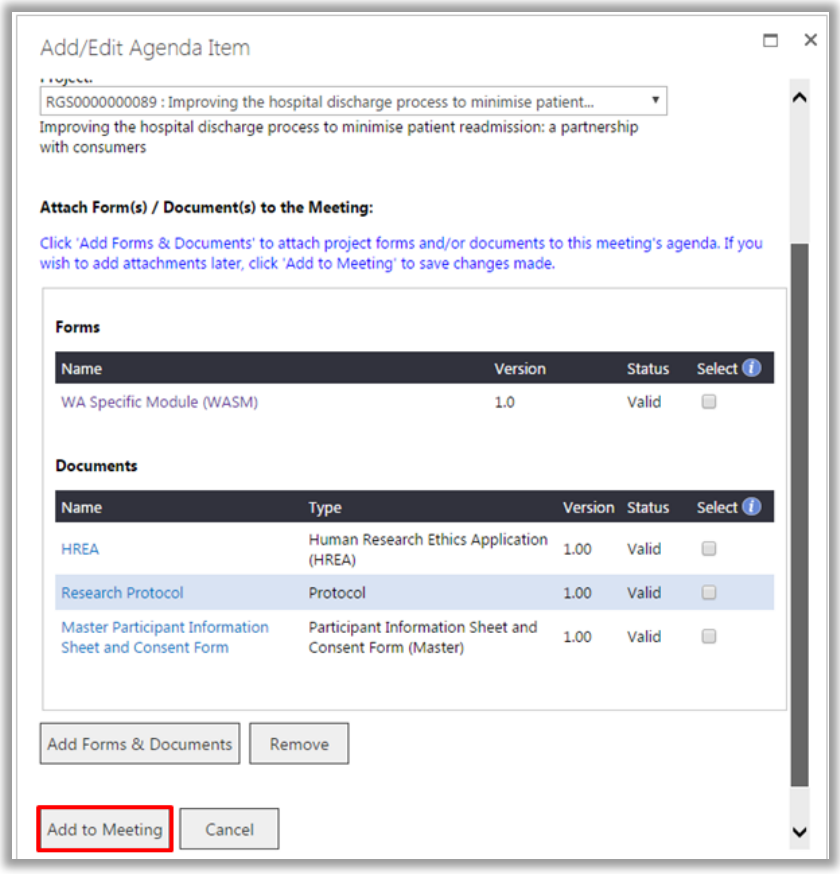


Note if you are still waiting the revised versions of the forms and documents from the project, you can skip this step of adding project forms and/or documents to the meeting agenda by clicking 'Add to Meeting'. The forms and document will not be available to the committee members until they are added to the agenda. You need to make sure that you attach them at least one day prior to the meeting date for them to be included in the review assessment.

In the 'Add Forms and Documents' screen, select the project's forms and/or documents you want to be added to the meeting and click 'Save'. Clicking 'Cancel' will discard any selection made.



You will return to the 'Add/Edit Agenda Item' screen. Click 'Add to Meeting' this will add the project and its forms and/or document to the agenda, it will not be saved to the agenda until you click 'Save' at the bottom of the 'Agenda & Minutes' tab. Clicking 'Cancel' will discard any changes made and the agenda item will not be added to the meeting.

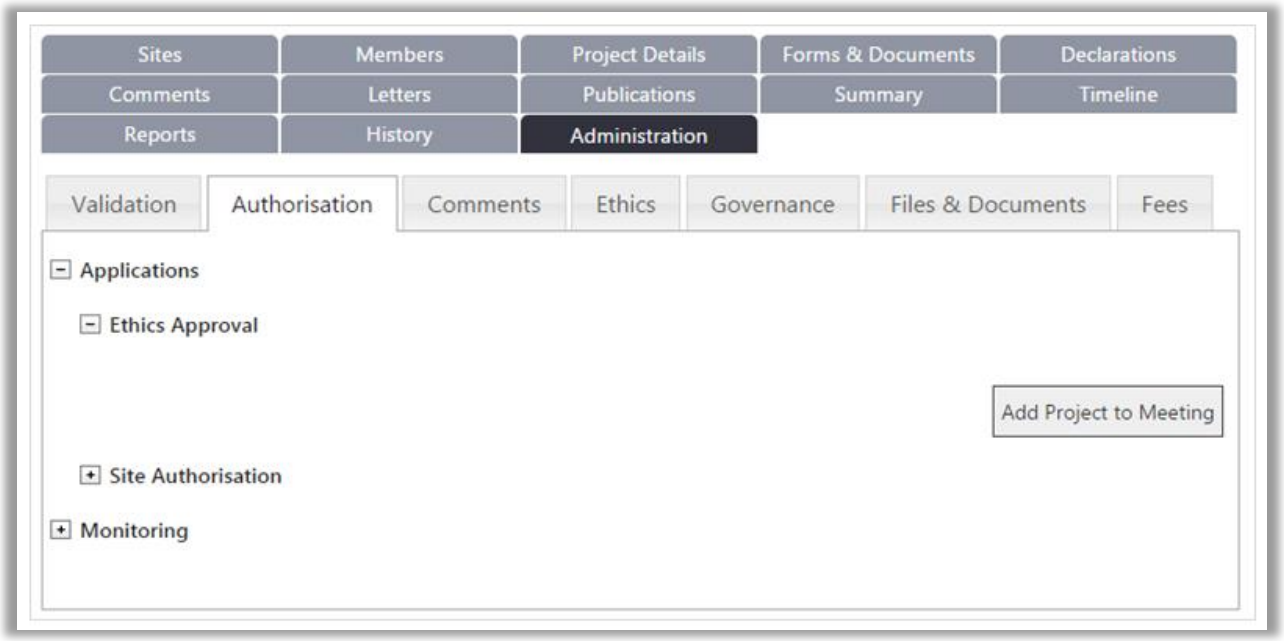


6.2 Add a project from the project workspace

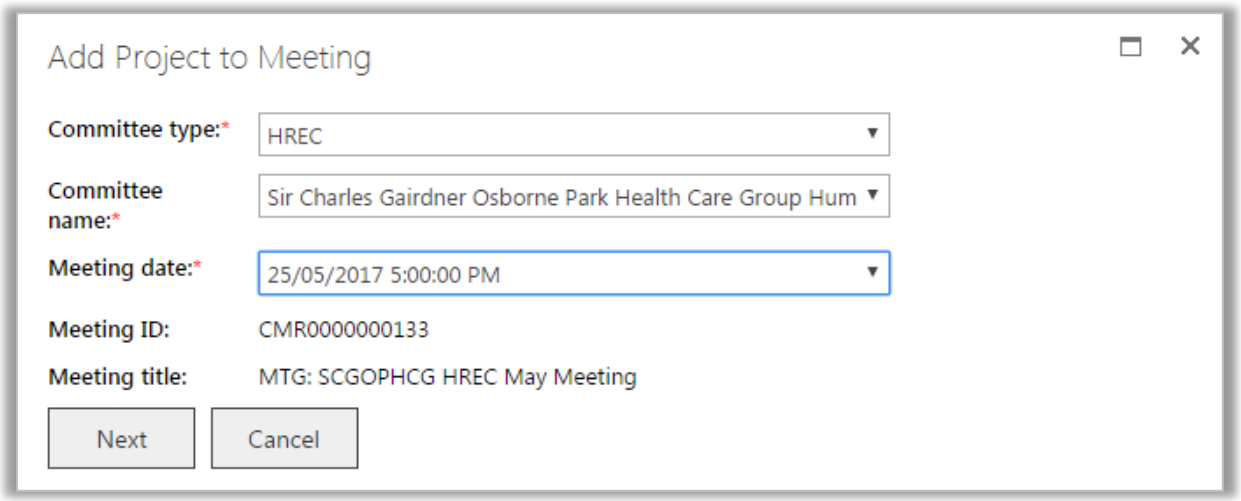
Adding a project to an agenda from the project workspace can be done straight after validation. To add a project to an agenda the following conditions will have to be met:

- At least one form or document from the submission has the status of valid. If there are outstanding form/documents for the project and they are not received in time the project can be removed at any time prior to the meeting.
- The meeting has been previously created. To create a meeting please go to Create scheduled meetings or Create ad hoc meetings.

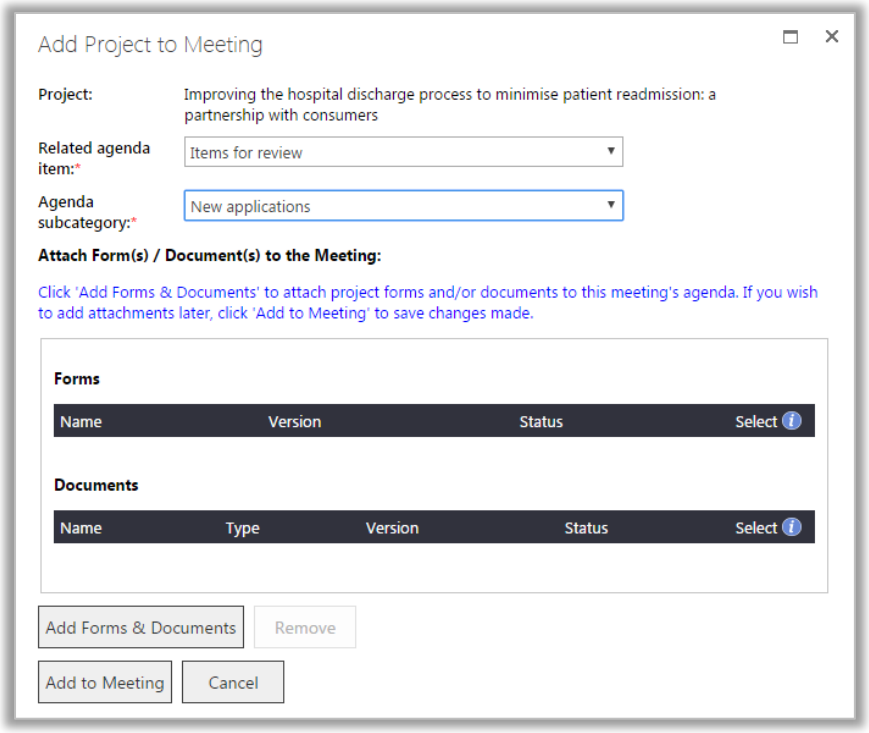
Go to the Authorisation tab. Expand Application and Ethic Approval, click 'Add Project to Meeting' button.



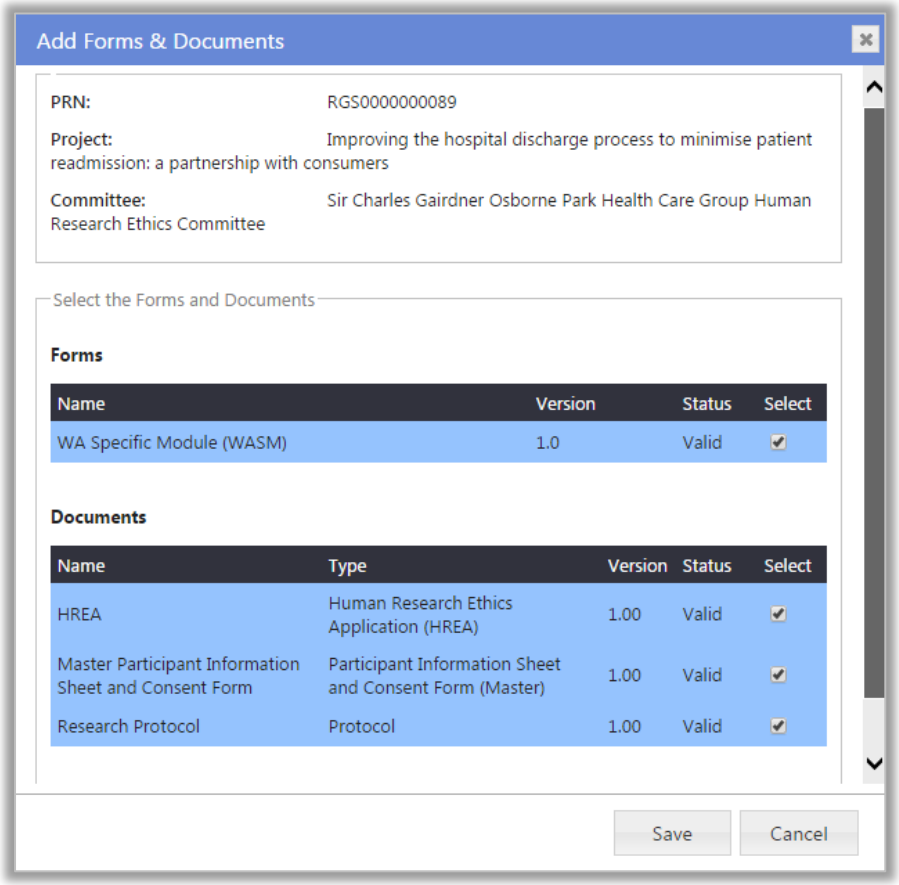
In the first screen you select the meeting details. You can only select from the committees that are associated with your Ethics Office. Each selection you make will narrow the selection in the fields below. When you have completed the information in the screen click 'Next'.



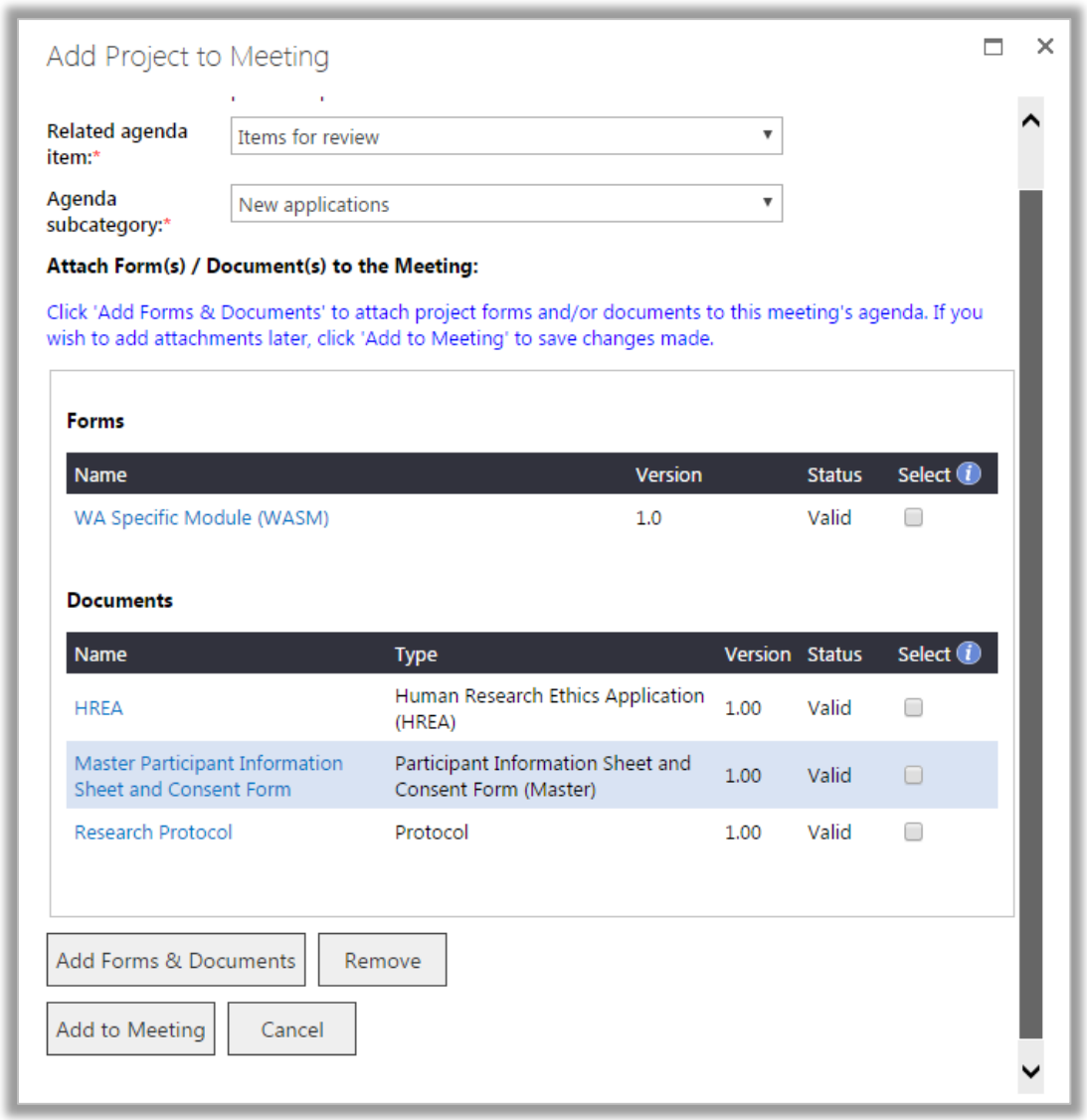
In the next screen you will have to select where in the agenda the project is to appear. For projects being reviewed prior to HREC approval, select 'Items for Review' with the subcategory of 'New Applications'. When this is selected you can add the forms and documents. Click 'Add Forms & Documents' and the screen below will appear.



You can add forms and documents that have the status of Valid, AIR SC Recommended. You can select any form or document, which allows for committee members to review previous versions of documents that have been AIRed alongside the new valid versions as part of the agenda. Select the form and associated document that are to be reviewed by the committee at the meeting and click 'Save'.



When you have saved you will be taken back to the previous screen. You can remove any or all of the forms and documents that are listed by selecting the item and clicking 'Remove'. If everything is correct, click 'Add to Meeting'. The project is now in the agenda and is accessible by any committee member who has been invited to that meeting.

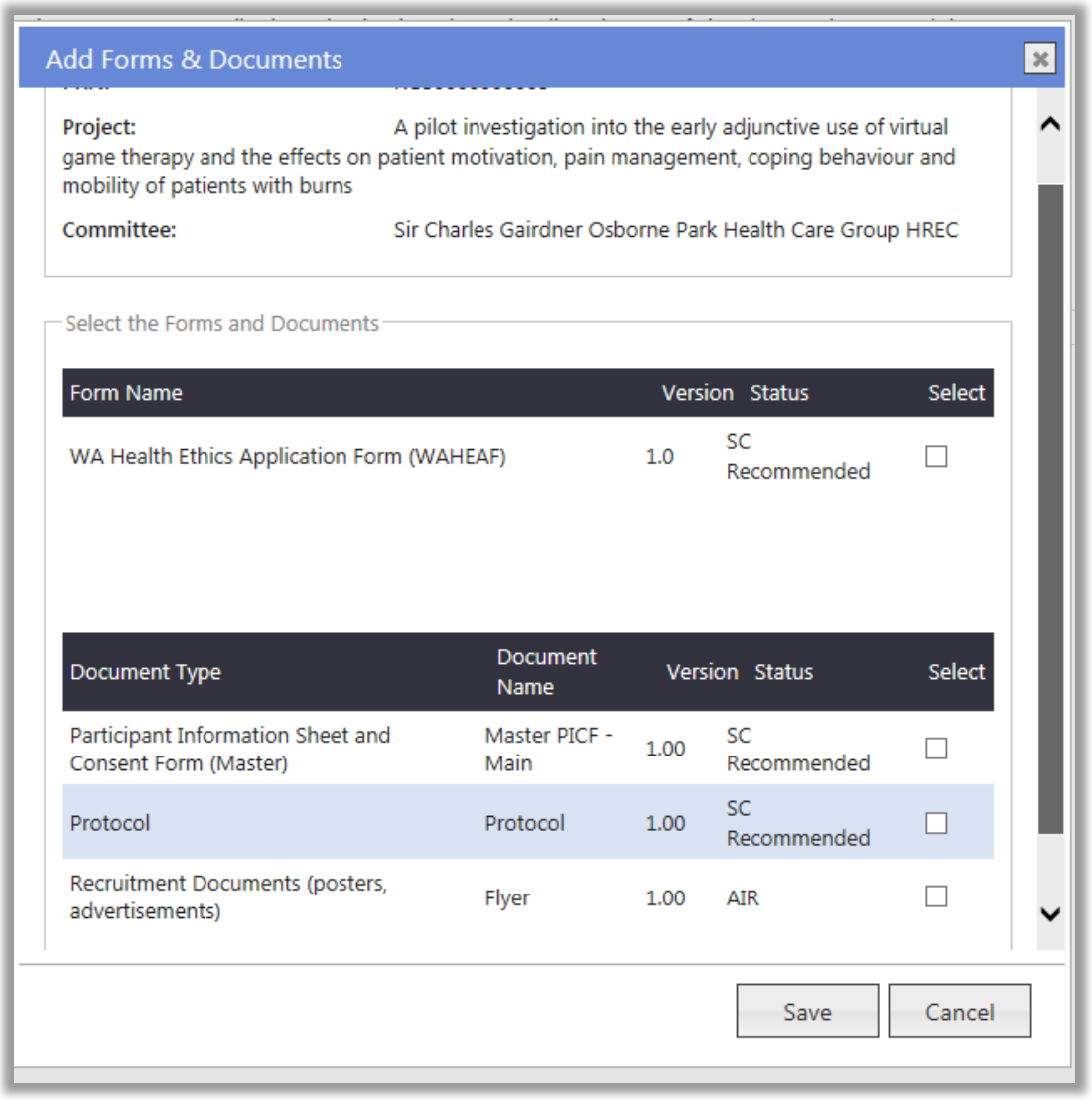


Note: Forms and documents or any other attachments should not be removed from the agenda after the meeting has started.

6.3 Add a project that has been to a Subcommittee

An ethics application that has been added to a subcommittee can also be added to the HREC. The process is the same as previously described either from the project workspace or access to the agenda from the calendar. The forms and documents shouldn't be added until after the review assessment of the subcommittee has been finished. You have the option of adding documents that were AIRed at the subcommittee if you want to. Once again you have the option of removing any document prior to the meeting but this shouldn't be done after the meeting has taken place.

If a project is added to the HREC agenda and is unsuccessful in being recommended for review by the subcommittee it can be removed from the HREC agenda prior to the meeting date.



6.4 Add other business

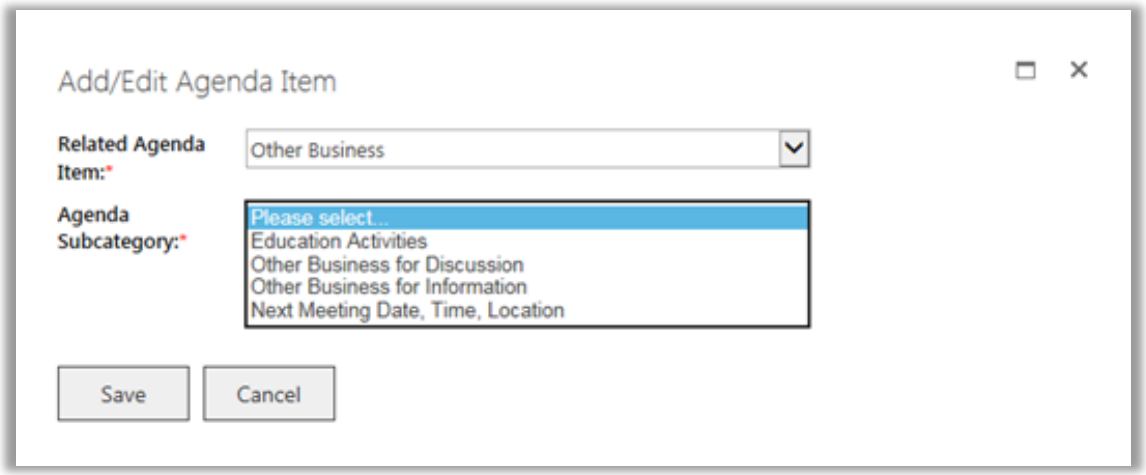
Other Business is a section of the agenda that can be used for agenda items that are not projects within RGS. There are four subcategories within Other Business these are

- **Education Activities** – this can be used to notify all committee members of education, seminars, presentation etc. that may be of interest to them.
- **Other Business for Discussion** – Individual or group items can be added here. This can be used prior to the implementation of monitoring in the RGS to itemise projects that the committee will be reviewing at the meeting.
- **Other Business for Information** - Individual or group items can be added here. This can be used prior to the implementation of monitoring in the RGS to provide a list of projects that

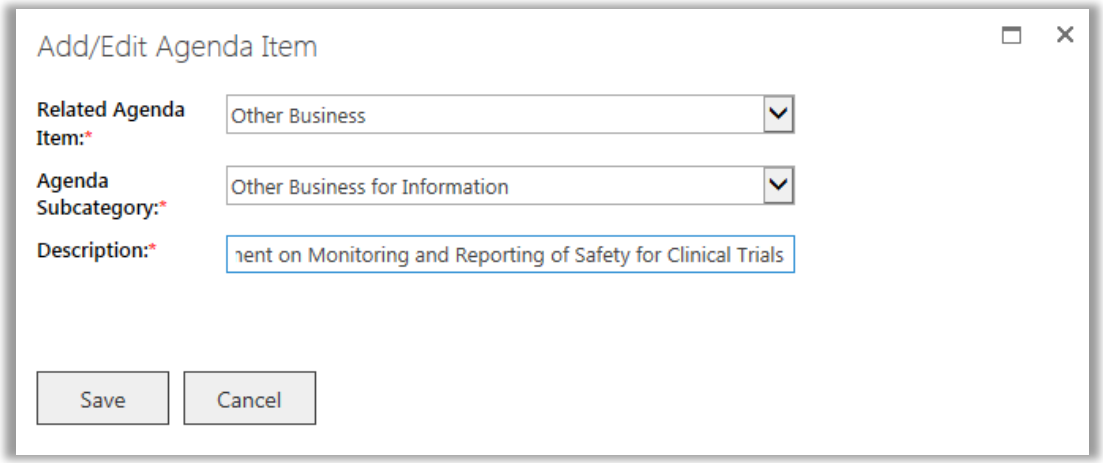
have been reviewed out of session and are only for the committee's information e.g. a list of approved amendments, progress reports, etc.

- **Next Meeting date, time, location** – the details of the next scheduled meeting can be added here.

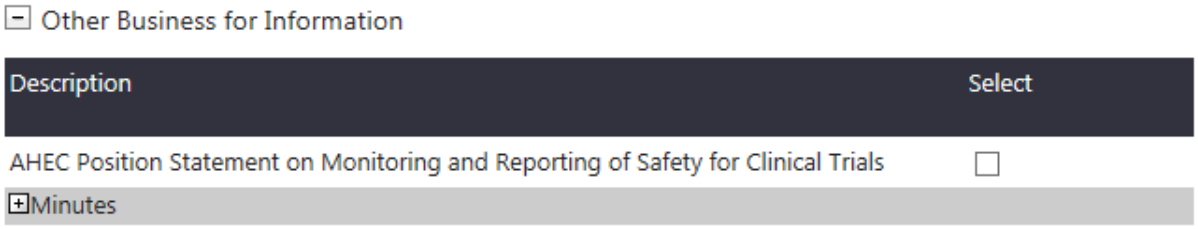
Select the Related Agenda Item first. There will then be a drop down list for the Agenda Subcategory. Select one of these.



When you have selected the Agenda Subcategory, the Description field will appear. Enter a description about the item and click 'Save'.



The item will now be in the agenda.

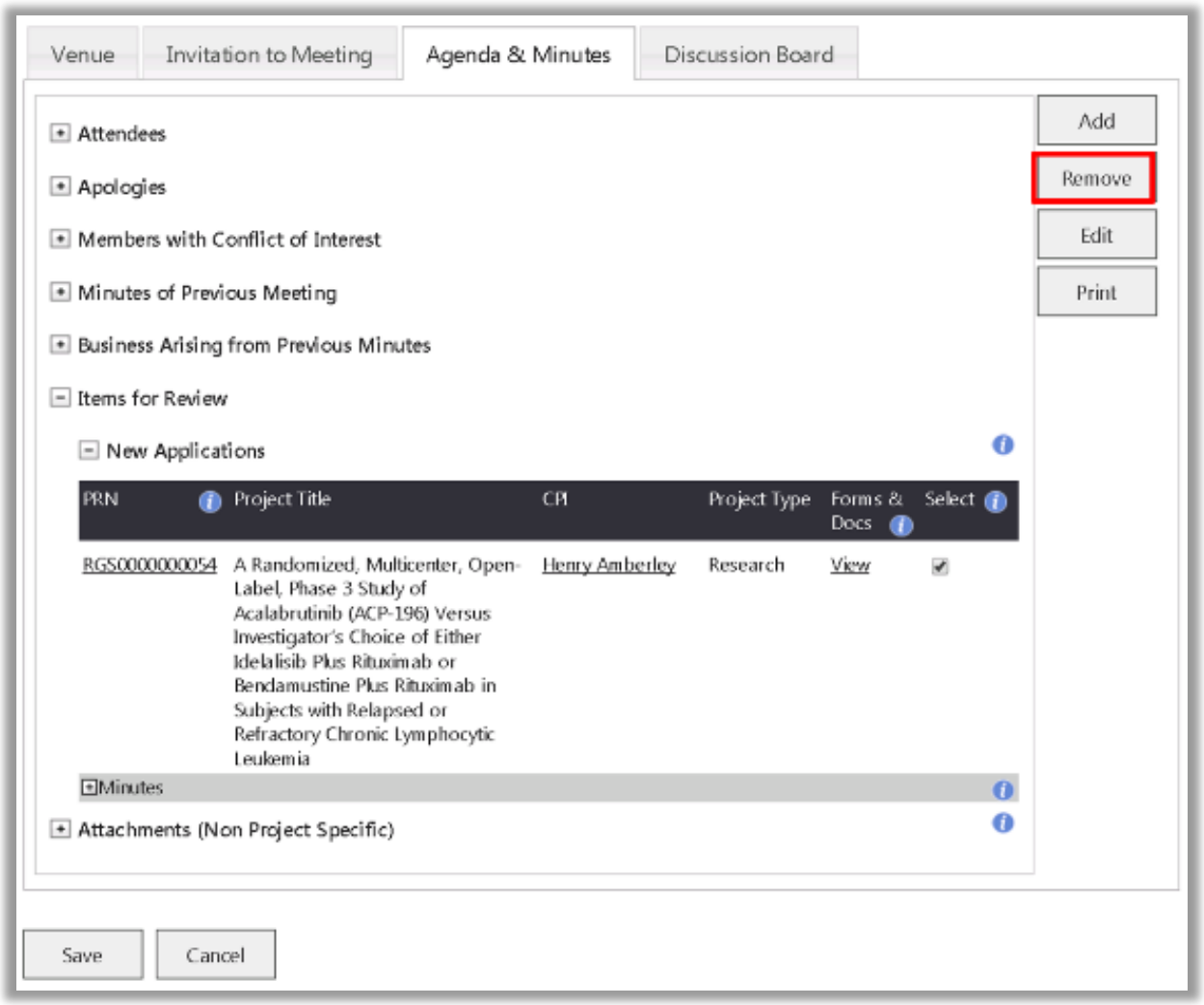


The change to the agenda will not take place until you click 'Save' at the bottom of the agenda screen. Clicking 'Cancel' will discard any changes made and the agenda item will not be added to the meeting.

If you wish to attach a supporting document to support this non project specific agenda item, refer to Attach a non project specific document section for the detailed steps.

6.5 Remove an agenda item

While in the 'Agenda & Minutes' tab of the Committee Meeting, select an agenda item you wish to remove, and click 'Remove'.



Click 'Save' to save any changes made, or click 'Cancel' to keep the agenda item.

Note while individual items can be removed from the agenda the following agenda categories have been added by default and cannot be removed:

- Attendees
- Apologies
- Members with Conflict of Interest
- Minutes of Previous Meeting
- Business Arising from Previous Minutes.

The optional agenda categories are:

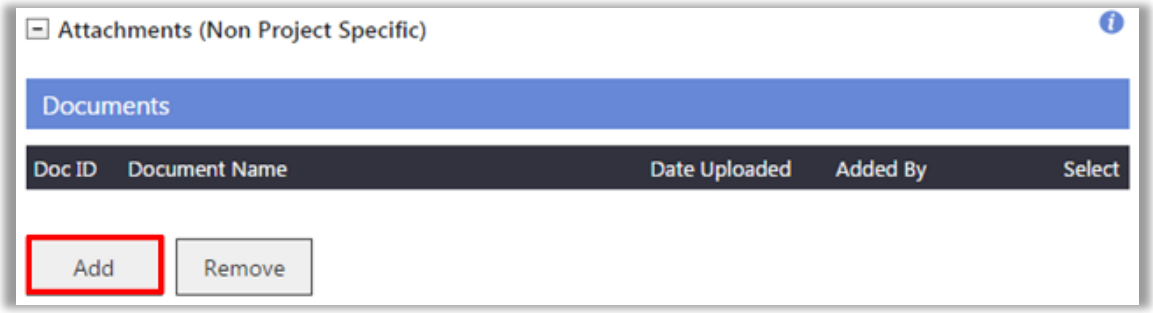
- Other Business
- Items Reviewed Out of Session.

These categories don't appear on the agenda unless an item is added to them.

6.6 Attach or remove a non project specific document

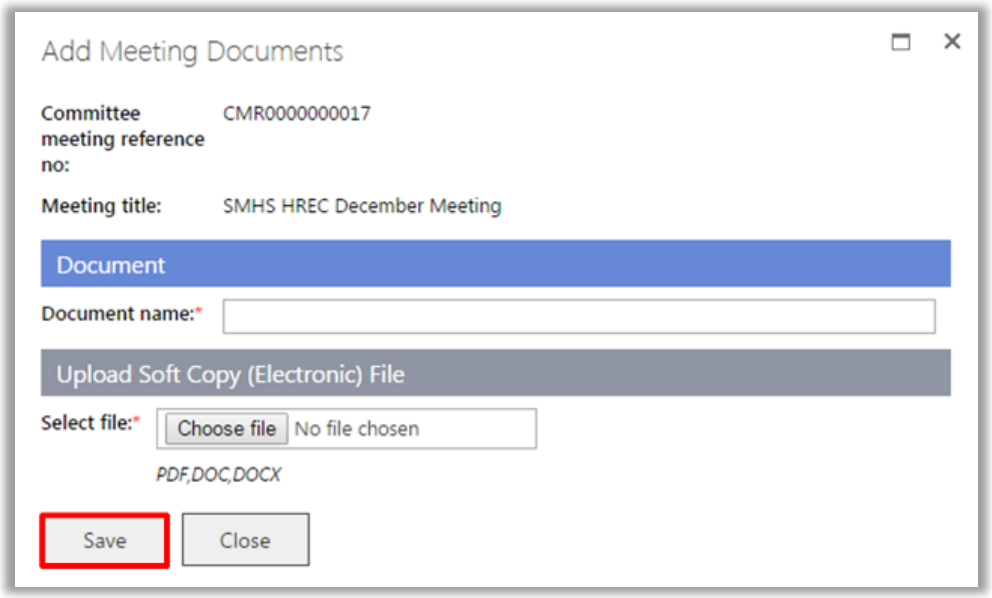
You may need to attach a non project specific document to support an agenda item under 'Other Business'.

Through the calendar, select the meeting you want to attach meeting documents to. Go to 'Agenda & Minutes' tab. To attach a non project specific document to a meeting, go to 'Attachments (Non Project Specific)' category and click 'Add'.

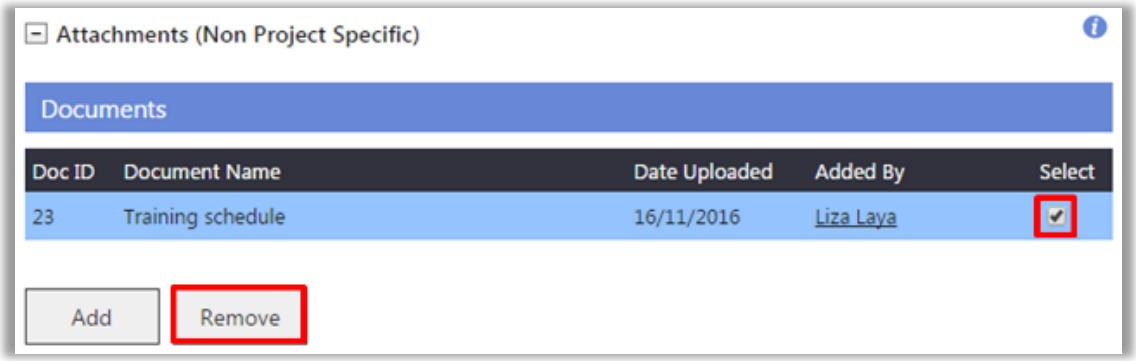


Enter the document name and attach the document. Click 'Save' and the agenda item will appear under its corresponding category.

Clicking 'Cancel' will discard any changes made and meeting document will not be uploaded to the meeting.



If you want to remove a previously uploaded document, tick the 'Select' checkbox and click 'Remove'.



7. Alternative Review

The Alternative Review gives the HREC the ability to review negligible and low risk projects outside of its normal meeting cycle. This Alternative Review can also be used when the HREC has delegated the review of a response to the HREC's request for additional information to a person or number of people to review and approve outside of the scheduled meetings. When Stage 2 is launched this can also be used for monitoring documents that are reviewed and approved on behalf of the HREC outside of the scheduled meetings. This is achieved by creating an Alternative Review Committee (ARC), only one needs be created for a HREC. Only a HREC can have an Alternative Review Committee this review process can't be used by a subcommittee.

Alternative Review meetings are always ad hoc meeting so they never appear on the public calendar. The people given the responsibility of conducting the review have to have the role of Committee Member under their user access as they have to be added to the ARC and invited to the meeting to review the application (these can be virtual meetings). This allows for a number of people to be members of the Alternative Review committee but not review every project.

A project reviewed by an ARC can still be attached to the HREC agenda as an Item for Review if required e.g. a low risk project is requesting a Waiver of Consent.

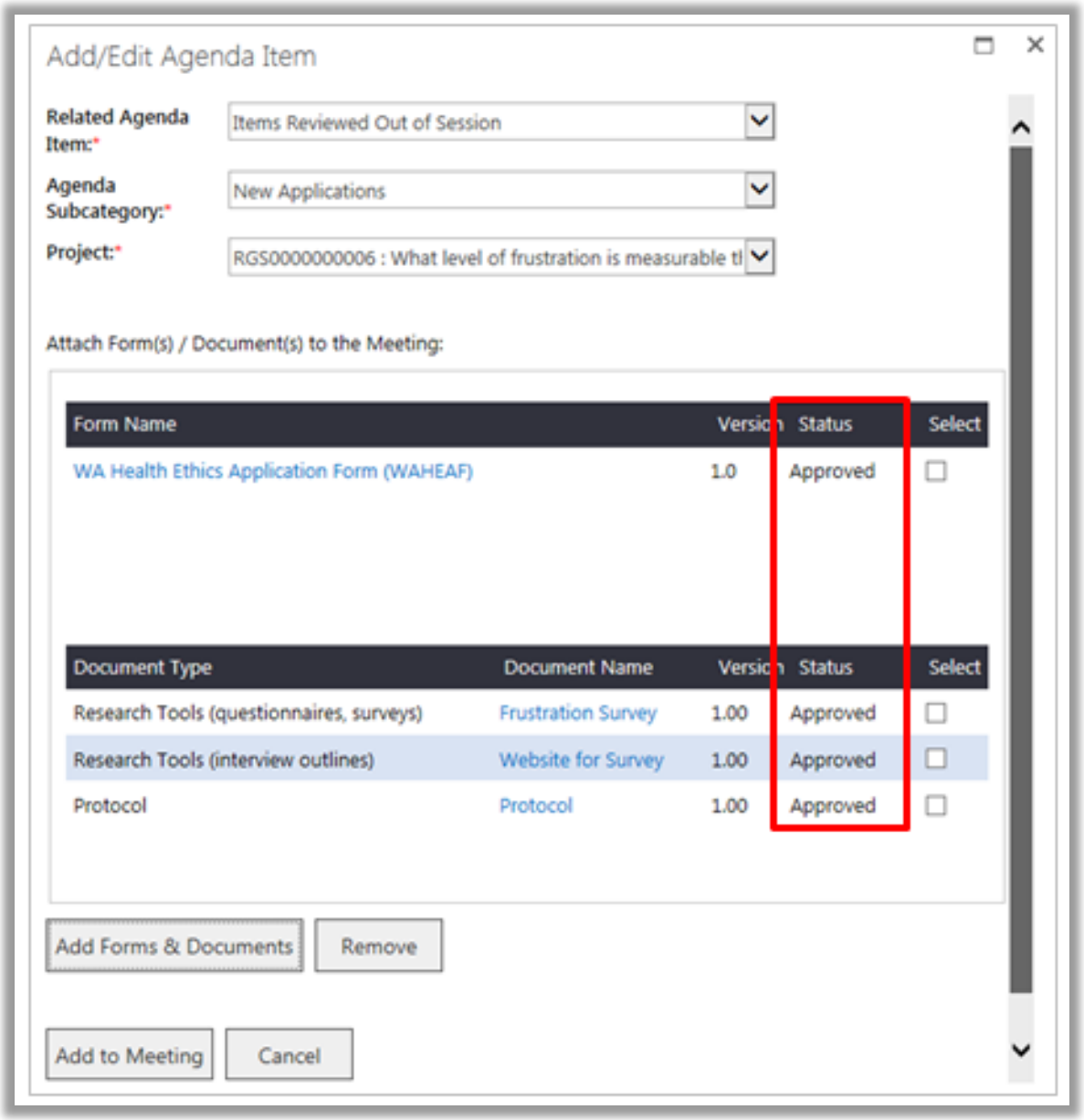
If reviews are regularly conducted you can create an Alternative Review committee meeting at regular intervals so that you can attach the projects to a meeting as soon as it has been validated. They are still created as ad hoc meetings and are only visible to the EEOsf and the committee members.

8. Add an Item Reviewed Out of Session

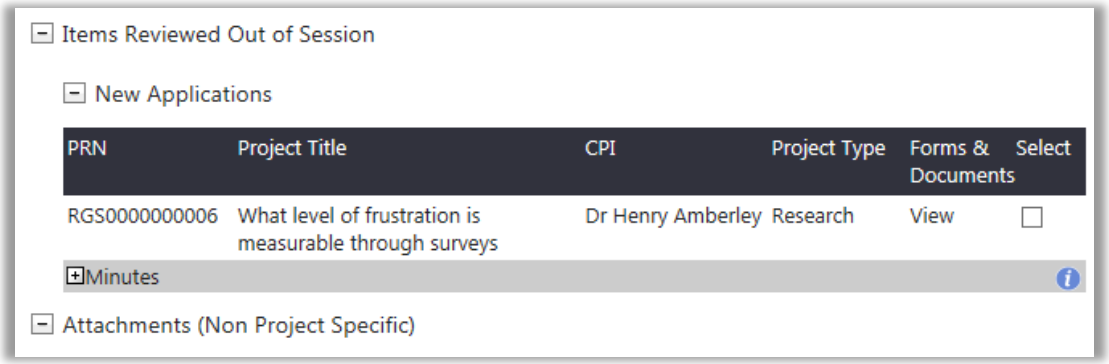
Items Reviewed Out of Session is used to record and inform a HREC of any research project that has been approved either by an Alternative Review Committee (ARC) or an Ad Hoc HREC meeting. It finishes the review and approval process for the HREC by listing the project so that the HREC members can (if they wish) look at any project that has been approved on their behalf outside of their scheduled meetings.

Research Projects should not be added to an agenda as Items Reviewed Out of Session unless the project already has been approved, once added no further review can be conducted on the project.

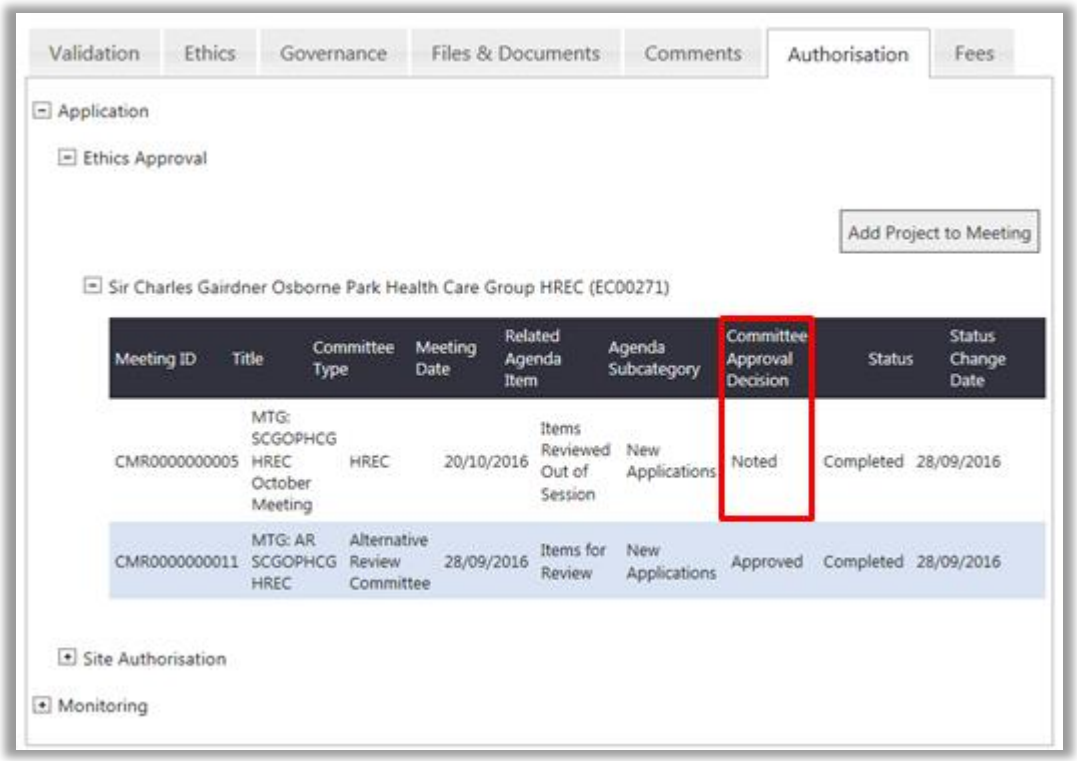
If project has been approved outside of the scheduled HREC meetings it can be added to the HREC agenda as an Items Reviewed Out of Session - New Applications and the status of the project and its forms and documents are approved. Do not add a project to this Agenda Item unless all the required forms and documents have been approved.



Once added to the meeting it appears under Items Reviewed out of Session.



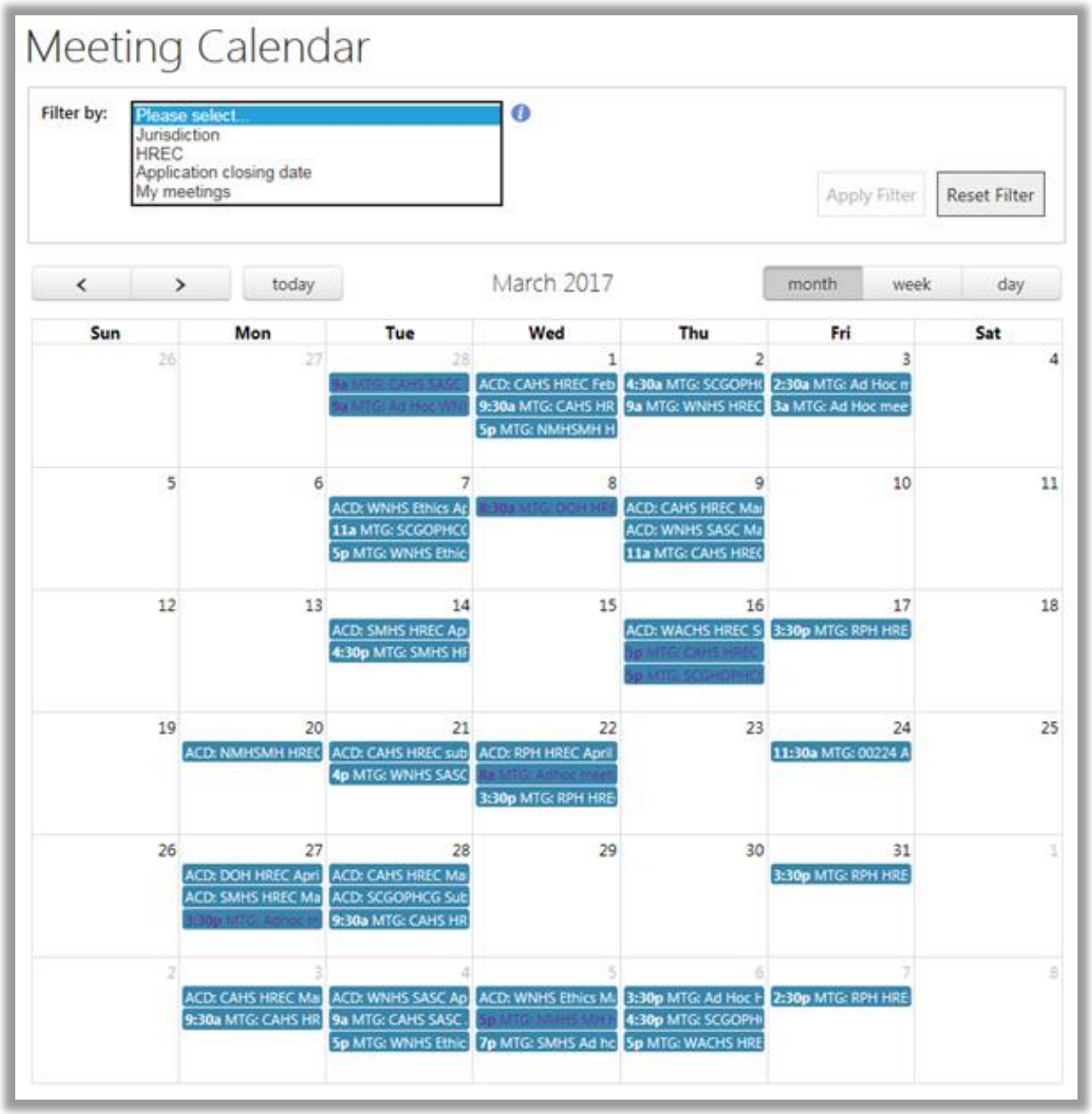
On the Authorisation tab it shows as Noted.



9. Create minutes of the meeting

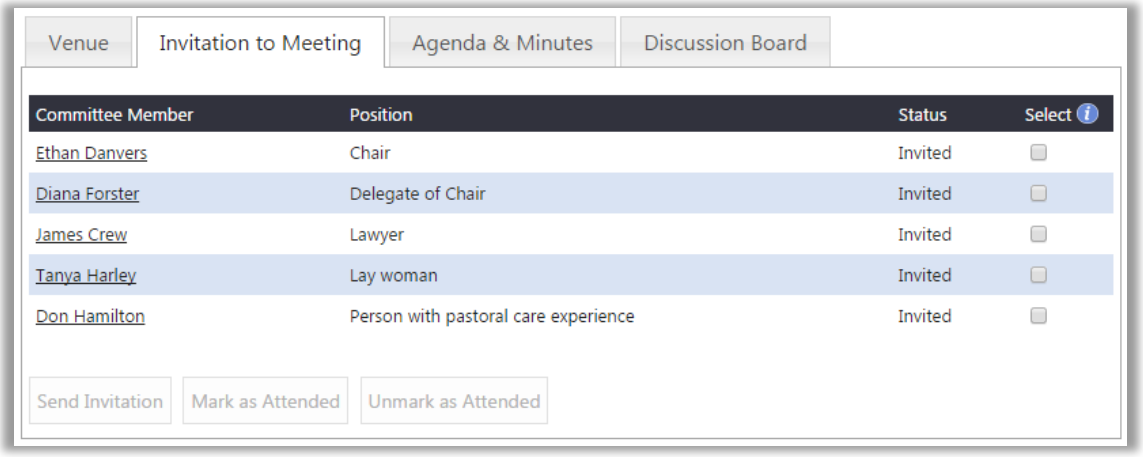
Each agenda becomes the minutes of the meeting after the meeting has finished. To access the meeting click 'Meeting Calendar' on the RGS menu found at the top of the page below the banner.

You can filter the calendar by the options below. Once you have located the meeting click on it, you can only open the meetings of committees that are assigned to your Ethics Office.

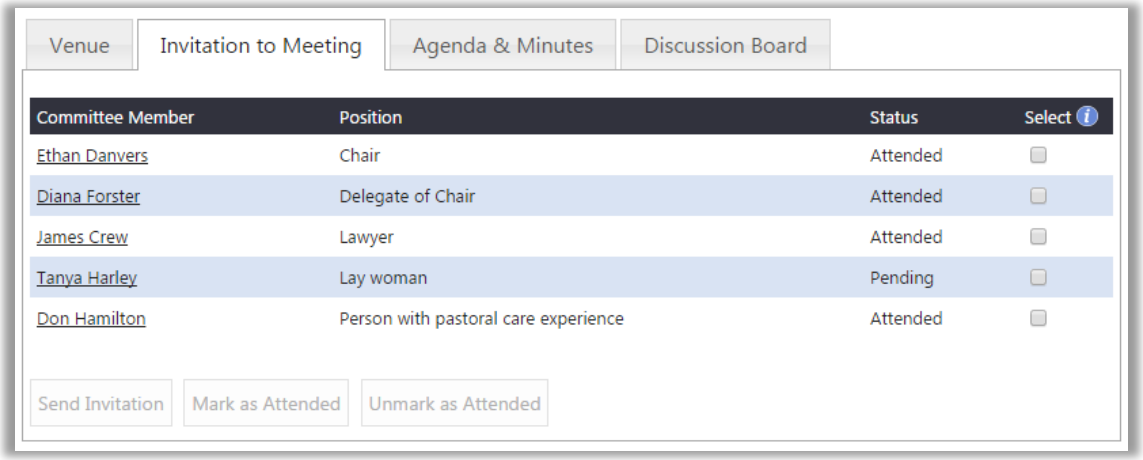


9.1 Mark committee members' attendance.

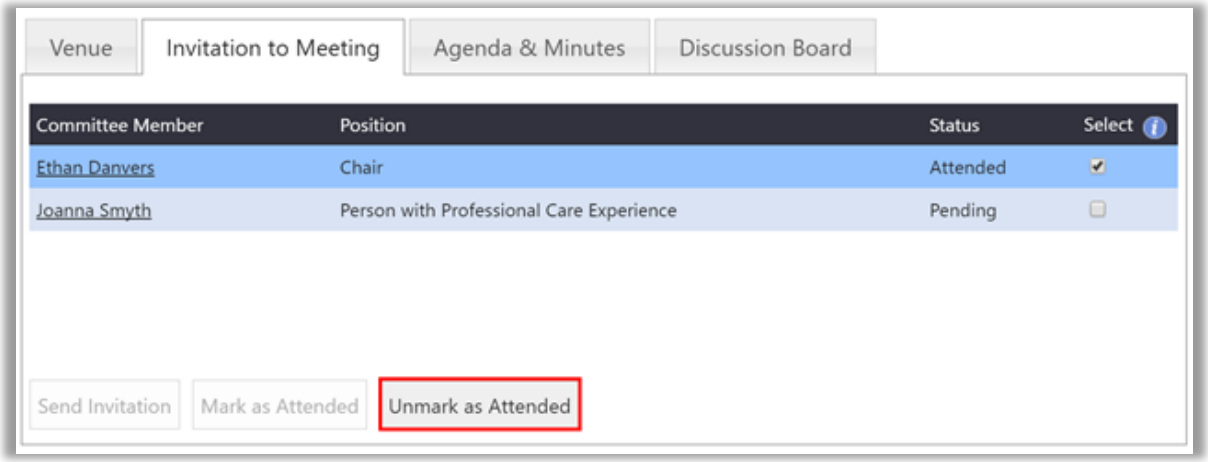
In the 'Invitation to Meeting' tab, members will either have the status of Invited or Pending. Members don't have to have been invited to a meeting you to mark them as attended. The Mark as Attended button will only become enabled after the meeting start time.



As with inviting member to a meeting you can select all the members you want and click 'Mark as Attended' and change all their status at the same time. All members marked as attended will then appear in the agenda under Attendees. Any apology from a member has to be entered into the Apologies section of the minutes.



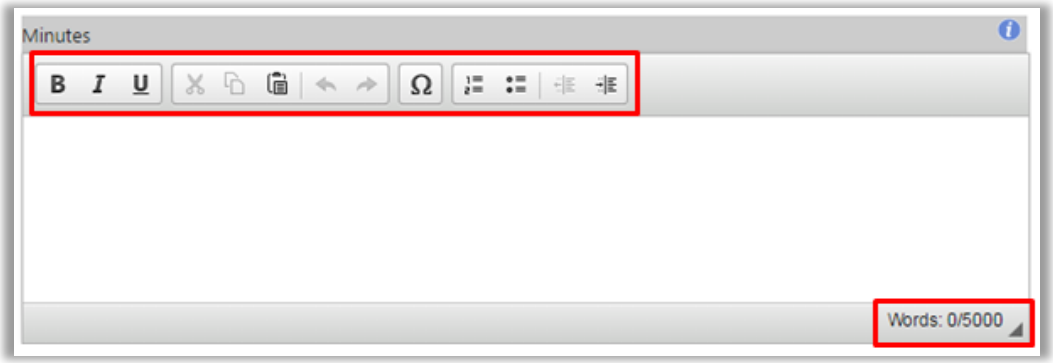
If a committee member has been marked as 'Attended' by mistake, you may change it back to 'Pending' by selecting the committee member and clicking 'Unmark as Attended'.



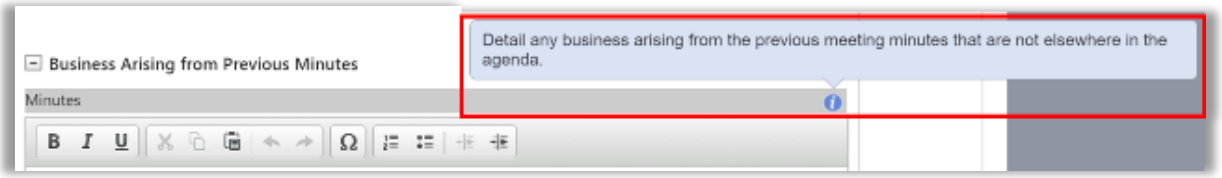
9.2 Adding the minutes to the agenda

Each text box that has been added to the agenda (when the agenda item is added) have the basic formatting functions in it to tailor the text, these are located on the top of each box. You can expand the minute's section by pulling on the triangle on the lower right hand of the box. In the border of the text box next to the triangle is the character count, there is a limit on the number of words available in each text box (5000). You can type the information into each item's minute section. You can also paste text into the text box. Once you start typing or paste text into the box it will tell you the number of words added. Please use this guide as you will get an error message if you go over the limit.

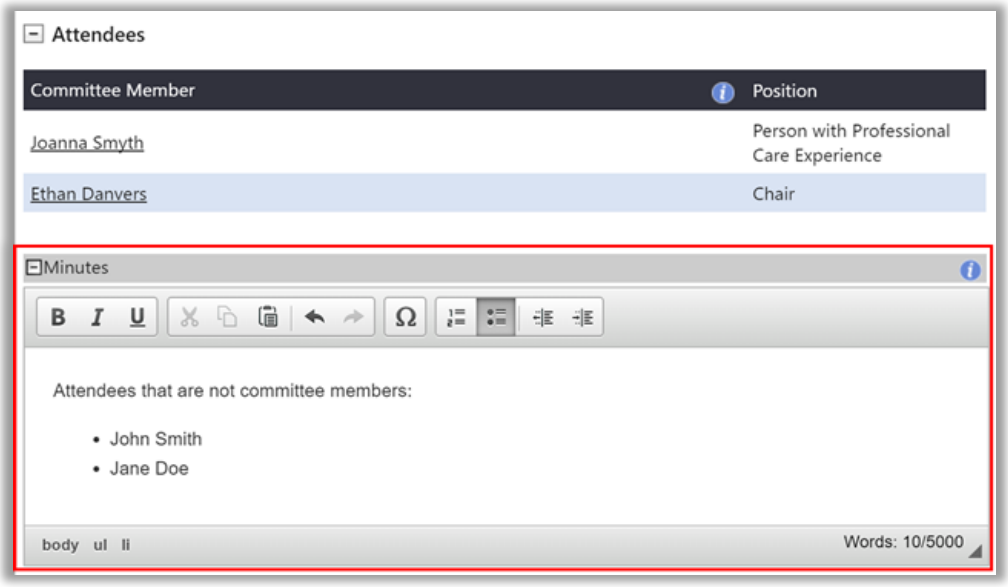
Please remember to save your work on a regular basis by clicking 'Save'. Once you have updated the minutes click 'Save' before exiting.



Each standard agenda item (Attendees, Apologies, Members with Conflict of Interest, Minutes of Previous Meeting, Business Arising from Previous Minutes) has a Minutes text box attached to it. The exception to this is Attachments (Non Project Specific) which is only for attaching documents to the agenda/minutes.
Click on the tooltips to read more information about the section or field to be completed.



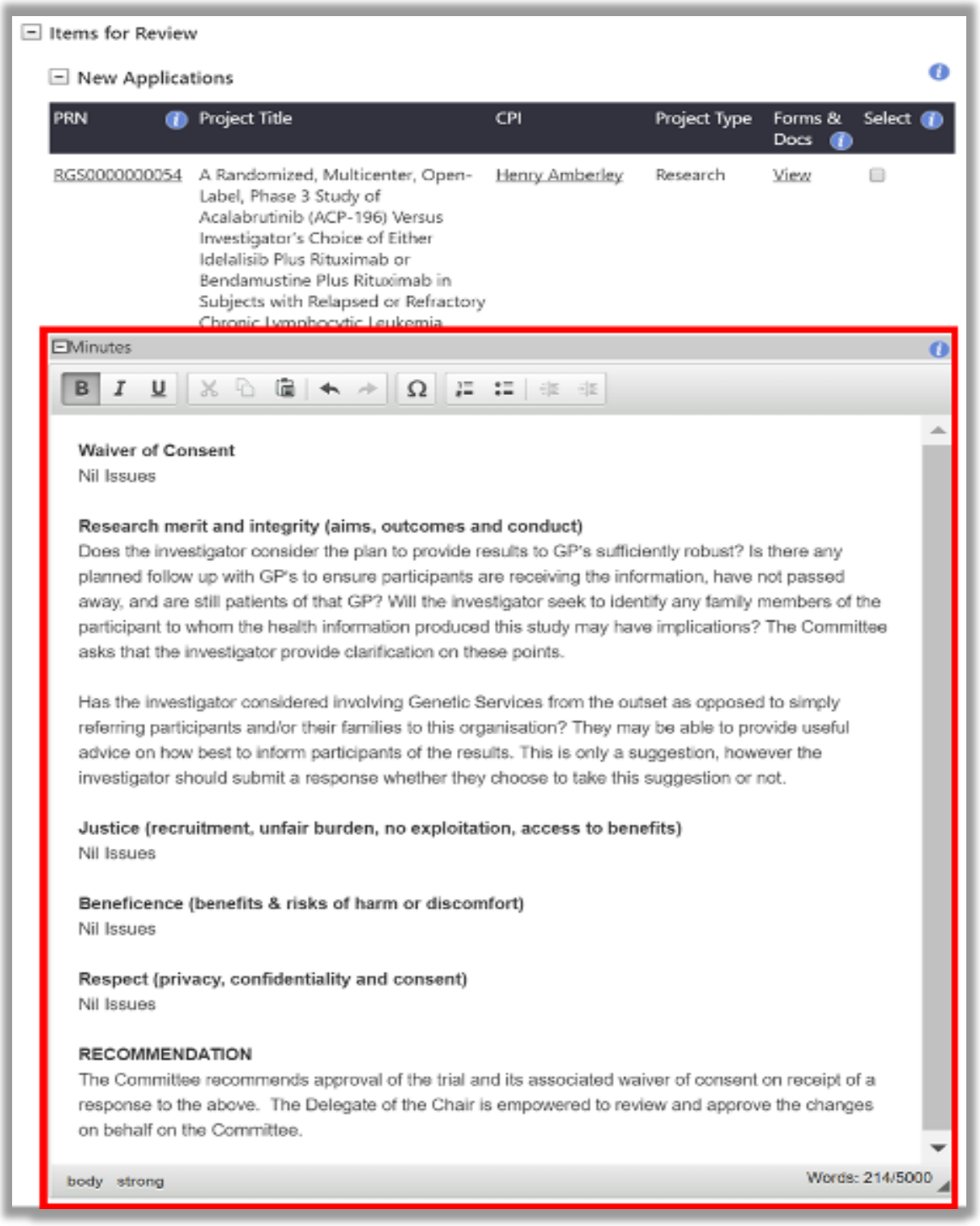
Expand this field by clicking on the plus sign [+]. In the example below, under Attendees, the 'Minutes' field allows for all attendees that are not committee members to be listed.



For minutes related to a project, minute the committee's review of the project. The following headings are recommended:

- Research merit and integrity (aims, outcomes and conduct);
- Justice (recruitment, unfair burden, no exploitation, access to benefits);
- Beneficence (benefits & risks of harm or discomfort);
- Respect (privacy, confidentiality and consent);
- Recommendation.

The information that is entered into the minutes against a project will appear in both the review assessment (not editable) and the letter to the CPI (fully editable).

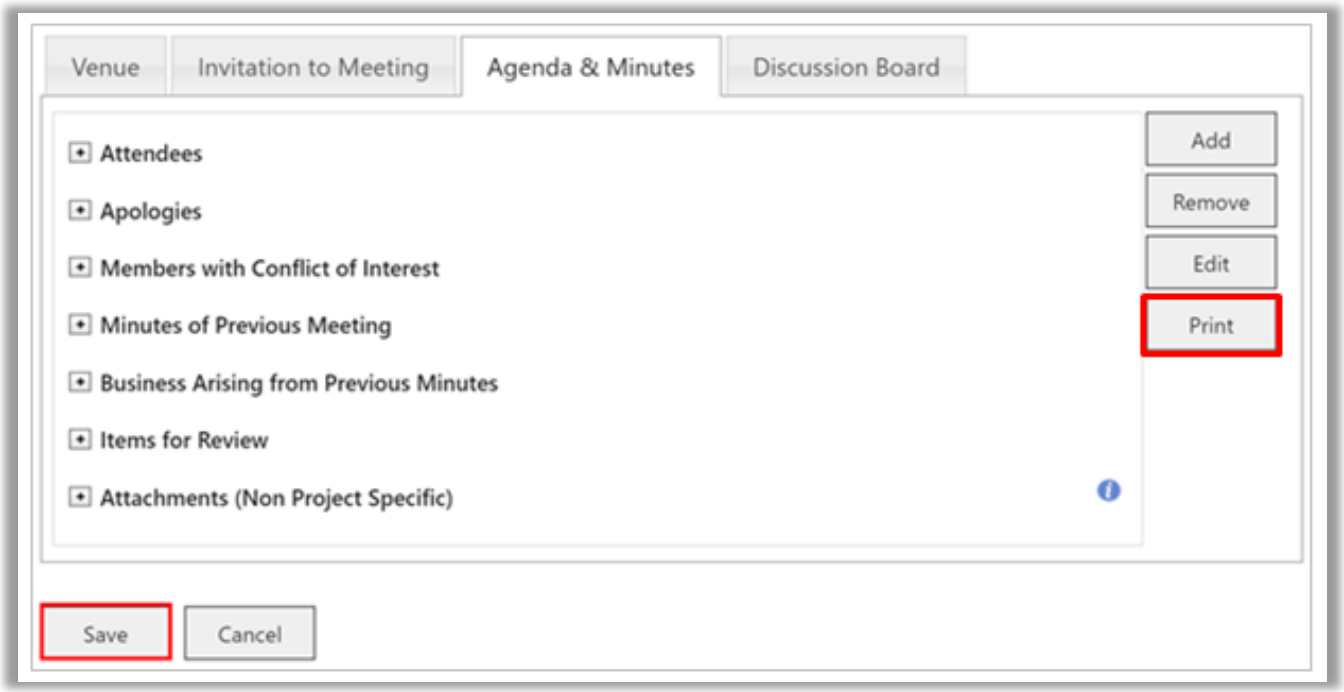


Click 'Save' found at the bottom of the screen to save any information entered, or 'Cancel' to discard them

The Chair can access the minutes through the calendar and review the minutes and make any changes. The Chair can also save the changes they make by clicking 'Save'. The minutes can be printed at any time by clicking the 'Print' button.

10. Print applications, agenda and minutes of the meeting

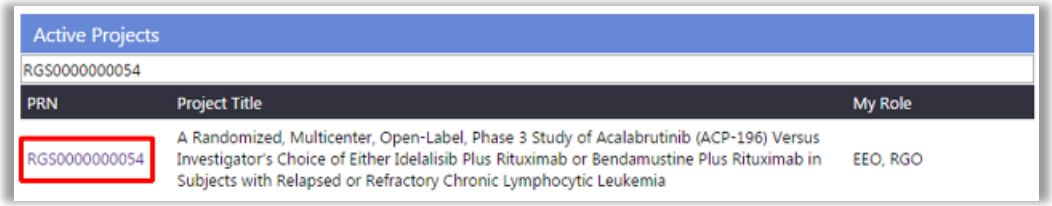
The RGS holds all forms and documents as well as the agenda and minutes of the meeting in a softcopy (electronic) state. As an EEO you can print any of these as long as you have access to them.



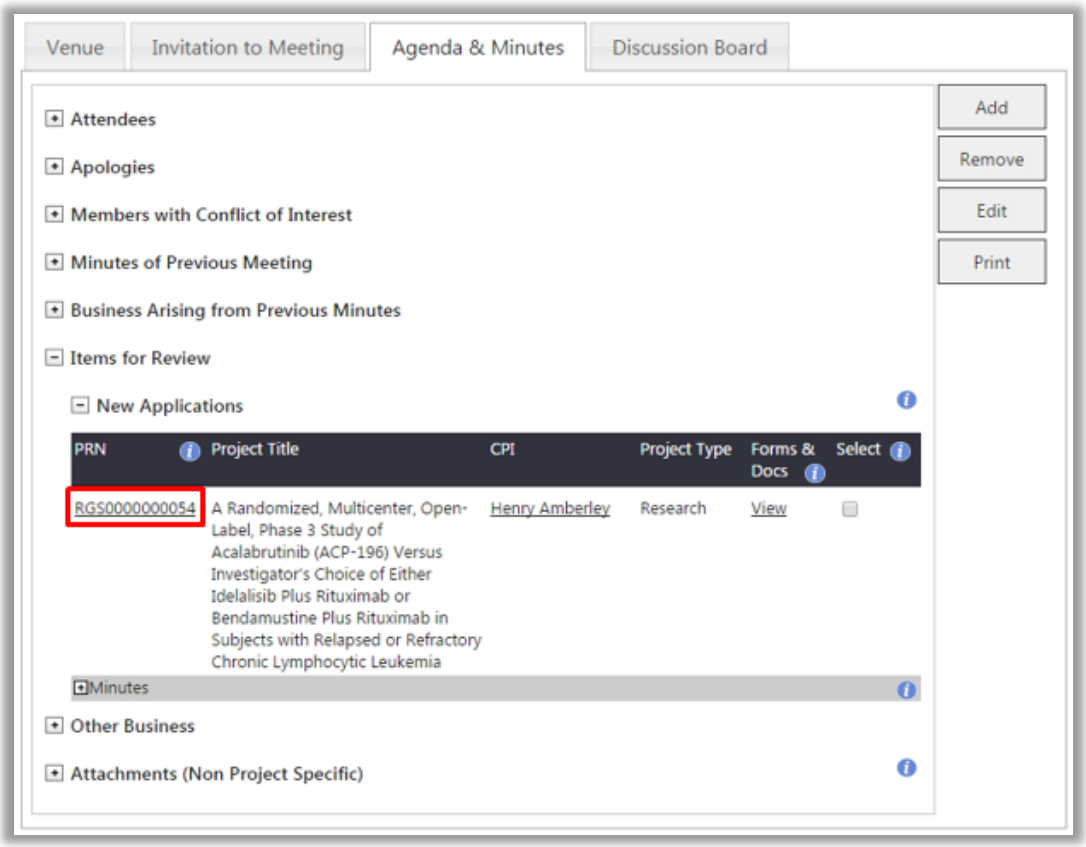
10.1 Print project application forms and documents

If any of the committee members require a hardcopy of the forms and documents of the project under review these can be printed from RGS.

To print the applications, you must be in Forms & Documents tab in a project's workspace. To get to this tab, you can either go by the My Projects screen:



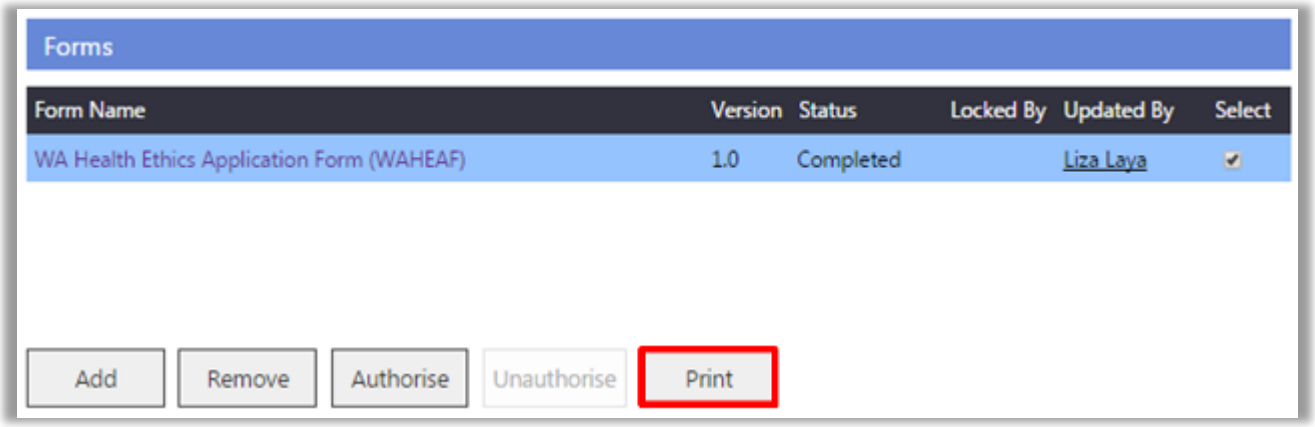
Or by clicking the embedded link in the PRN within the Agenda and Minutes tab of a committee meeting:



It is assumed that the project has been added to the meeting. Refer to Manager a meeting agenda for the detailed steps.

While in the project's workspace, click on the Forms & Documents tab.

You may click 'Print' within the project workspace's Forms & Documents tab after selecting a form or document:



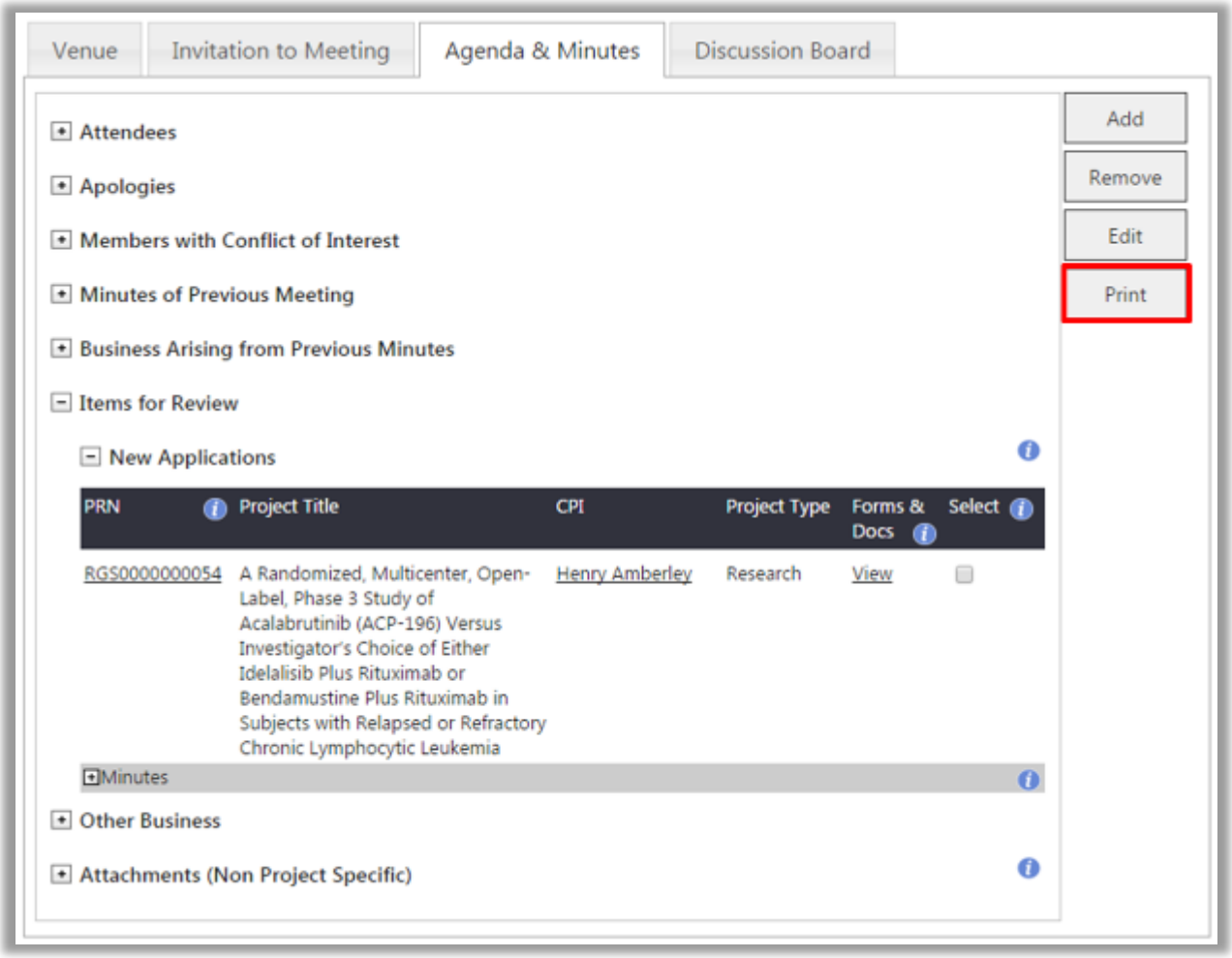
Or within the form itself:

A print preview of the form or document will be shown on a separate tab within your web browser.

Follow the appropriate instructions for your browser's 'Print' feature to print the webpage. If you cannot find the instructions for your specific version or browser, search your browser's Help menu for "print a page".

10.2 Print Agenda and Minutes of a meeting

Click on a meeting in the Meeting Calendar page. Go to the Agenda and Minutes tab of the committee meeting.



A print preview of the agenda and minutes page including the committee meeting's header and venue details will be shown on a separate tab within your web browser.

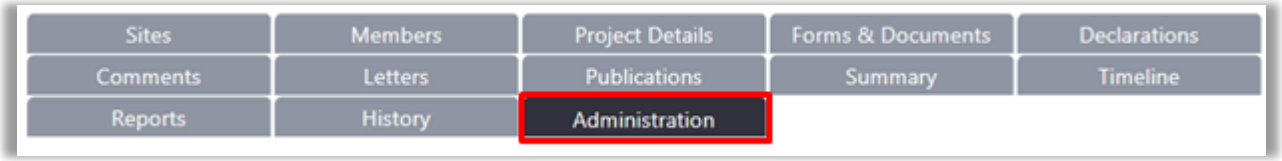
Follow the appropriate instructions for your browser's 'Print' feature to print the webpage. If you cannot find the instructions for your specific version or browser, search your browser's Help menu for "print a page".

11. Manage committee review and approval, including letters

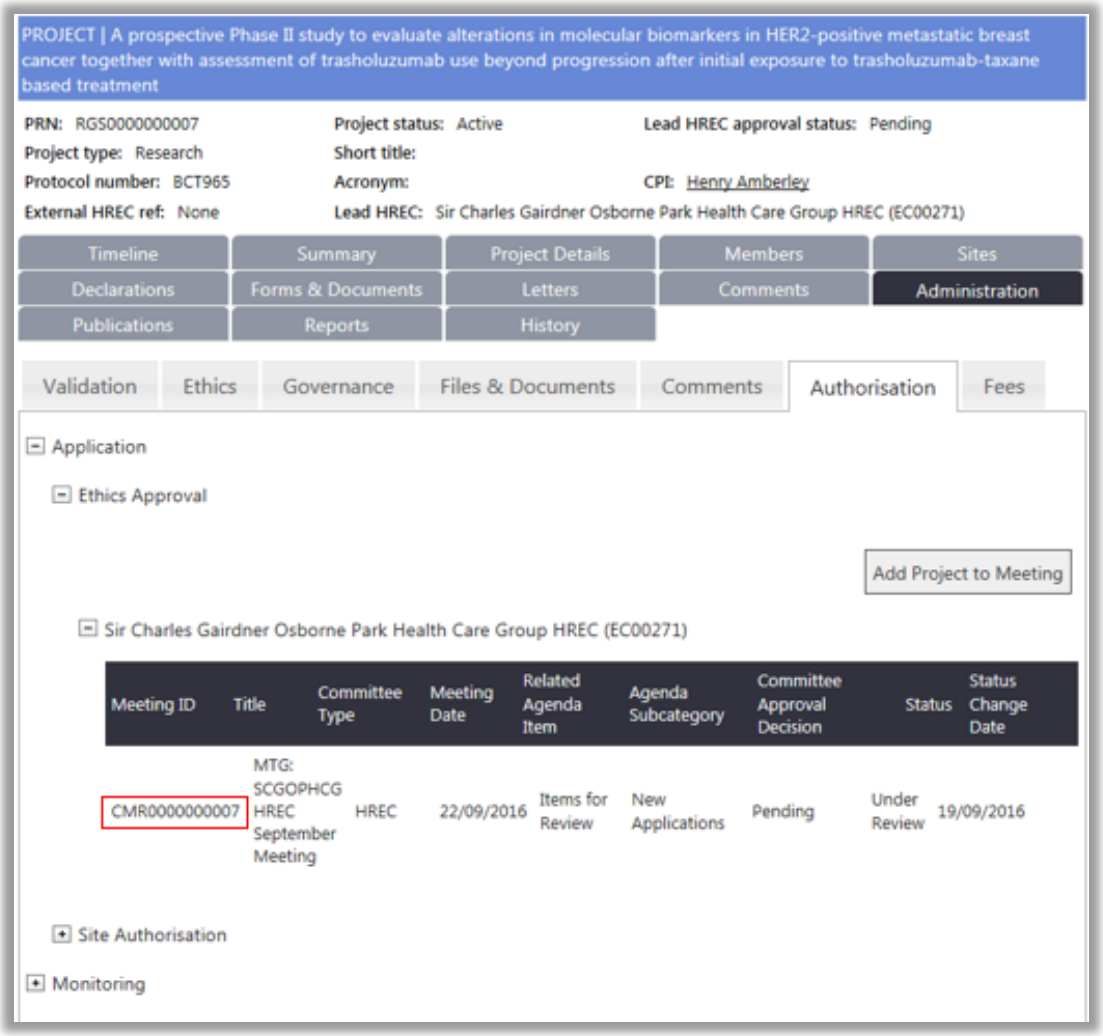
You can access the individual projects through My Projects (the menu on the left-hand side of the screen) or if you are in the meeting agenda/minutes by clicking on the project number.

11.1 Provide review assessment

After the meeting minutes have been reviewed by the Chair you can finish the review and notify the CPI of the outcome. To do this go the Authorisation tab, which is under the Administration tab in the project workspace.



Select the Authorisation tab. You are now in the same screen that you would have used if you added the project to a meeting. Click on the Meeting ID and the 'Provide Review Assessment – Forms & Documents' screen will appear. This screen will only appear after the meeting has past.

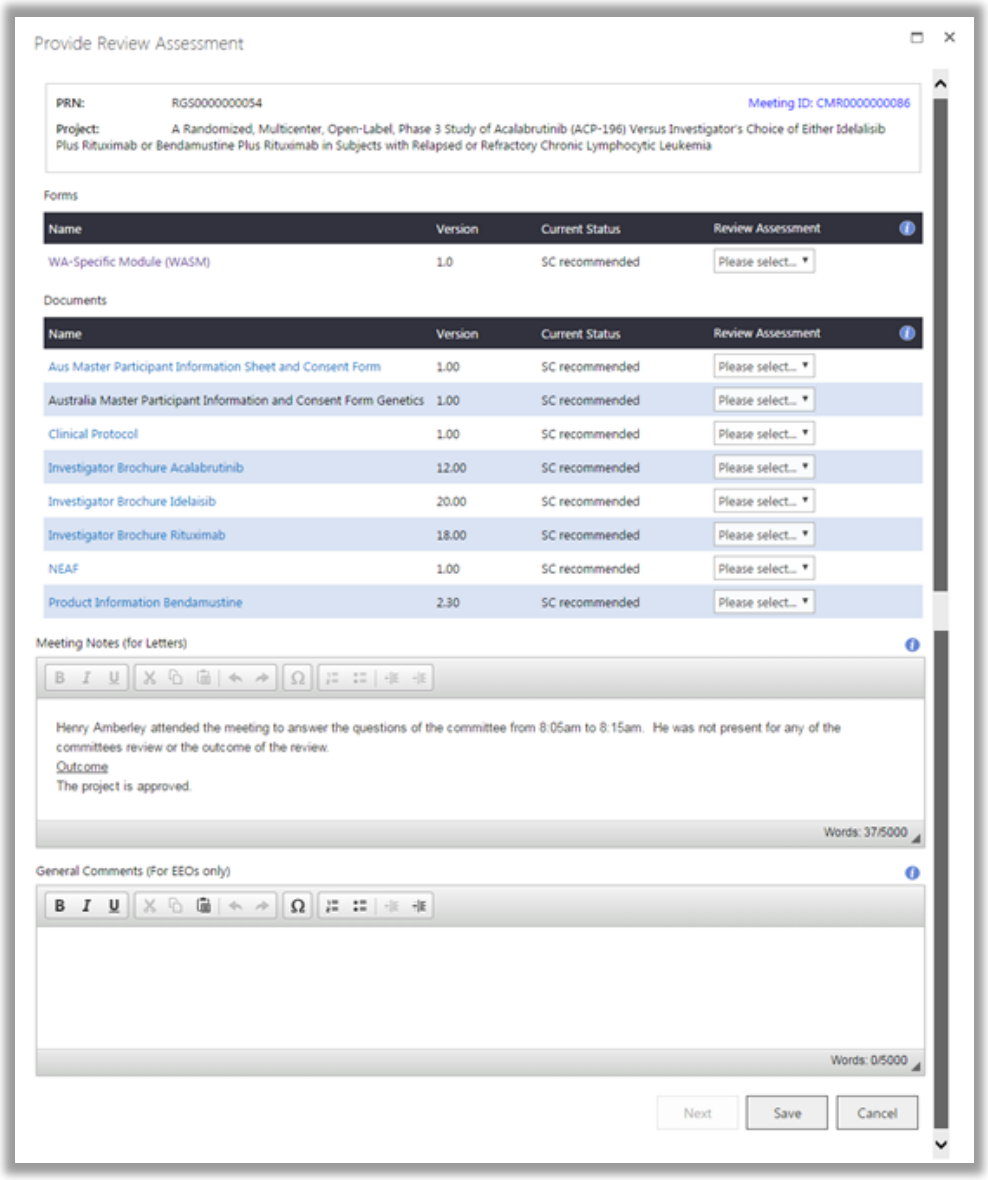


The Provide Review Assessment screen enables you to provide more detail to the project's forms and documents. There are three sections to this screen.

- The first section is the forms and documents where you can give each one its own assessment.
- The middle section is the Meeting Notes (for letter) this is the minutes of meeting of that project so you don't have to refer back to the minutes for the Committee's review and

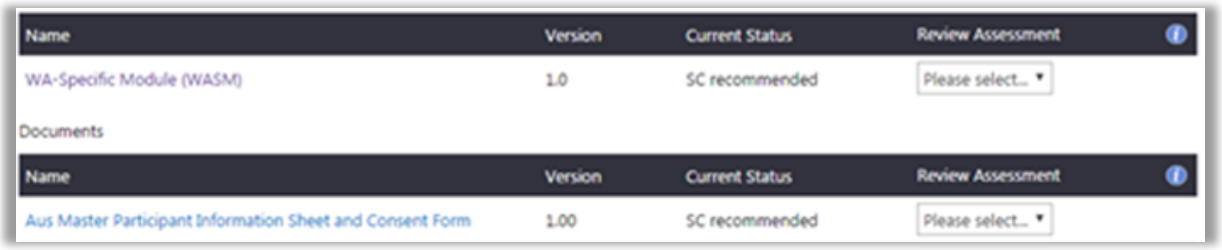
decision. These Meeting Notes are not editable however when they appear in the letter to the CPI there are.

- The last section is General Comments (for EEOs only) where you can leave a comment that is only visible to other EEOs from the same Ethics Office. This is useful if you need any reminders about the project that you or the other EEOs need to know.



You will need to provide an assessment for every individual forms and documents submitted for review. You may click on the embedded link in the name to open the form or download the document if you need to sight it. The document version is also provided.

The Current Status show the status of the forms and document prior to the meeting in the view below it shows that the project was recommended for HREC review by the Subcommittee. If there has not been a subcommittee review then the forms and document will have the status of valid.



The options for the review assessment are:

- **Additional Information Required (AIR)** – the committee have requested that there needs to be changes made to the form or documents. If this assessment is given to a form, a new version of the form will be placed in the Active section of the Forms and Documents tab. If this assessment is given to a document a placeholder will be created in the Active section of the Forms and Documents the CPI already has the document that they uploaded so it doesn't need to be provided to them.
- **Under Review** – if there doesn't need to be any additional information provided to a form but a document has been given the status of AIR then the form should be given the status of Under Review. This is to allow for the resubmission of the document through RGS.
- **Noted** – if the document was submitted and provided information only and is not part of the research documents (e.g. reply to HREC queries, tracked changes documents) then it can be given the assessment of Noted and will not be included in the list on the letter.
- **Approved** – if a document has been approved by the Committee it can be given that review assessment even if there are other documents or forms that do not have that status. A form should not be given that status unless all the documents have been approved.
- **Not Approved** – this should only be used if a Committee has decided that the document should not be used in the research project as no placeholder will be created for it and it is the stop point for the document. This should only be used for a form if the Committee has decided that the project will never gain approval from the Committee as it can never be resubmitted to that Committee.

If the review assessment is from a subcommittee of a HREC then the options are:

- **AIR** – additional information is required to be provided by the CPI. This doesn't prevent the ethics submission being put on the HREC's agenda.
- **Under Review** – this works the same as it does for the HREC and allows for the resubmission of the document/s through RGS to the subcommittee while maintaining the form for further review, this status can also be assigned to a document for the same purpose.
- **SC Recommended** – if the subcommittee has no issues or concerns for a form or document. It can be given this review assessment even if there are other documents that are given the status of AIR or Under Review.

Meeting Notes - The minutes from the meeting have been populated from the meeting. Hence, there is no need to refer back to the minutes for the Committee's decision. This information will then automatically populate the letters, where it can be edited before being sent to the CPI.

General Comments – Provide a comment that is viewable only by other EEOs from the same Ethics Office. This is useful if you need any reminders about the project that you or the other EEOs need to know.

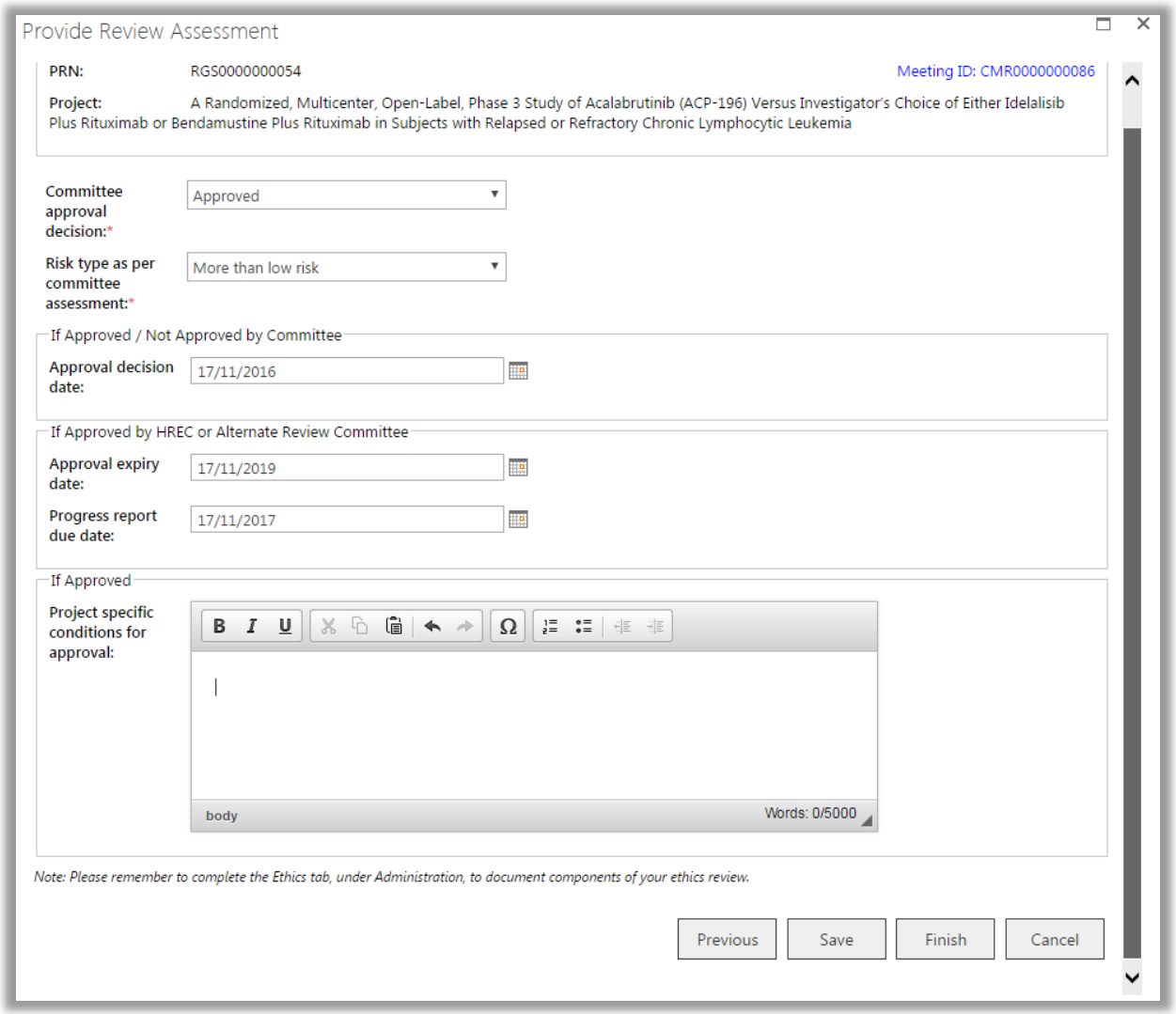
Once the review assessment has been decided and you have added any comments for yourself or other EEOs in your office you can press the 'Next' button. This button will only become available after the review assessments have been given for each form and document reviewed at the meeting.

11.2 Provide the Committee's decision

The next screen will provide the overall assessment of the project by the Committee.

The Committee approval decision is the overall review decision by the committee the options are:

- **AIR** – if the Review Assessment on the previous screen was AIR for the form or any document then the Committee approval decision will default to AIR. This decision would be used if the Committee has given in principle approval to a project subject to clarification by the CPI and/or changes in the project's documents.
- **Approved** – if the Committee's decision was to approve the project with no further communication with the CPI required this should be selected, it can only be assigned if the Review Assessment against the form and documents is either Approved (for the HREC or Alternate Review Committee) or SC Recommended (for the subcommittee). When this is a decision of the Subcommittee then the bottom half of the screen will not appear and the risk type and the approval decision date will only need to be completed.
- **Not Approved** – this should only be selected if the Committee's decision was that the project should not be conducted and will not be resubmitted to the Committee. All forms and documents should have been marked as not approved in the previous screen before it is selected in this screen. This option ceases the review process and the project will have the status of not approved.



Risk Type - The 'Risk type as per committee assessment' this defaults to the risk assessment given by the CPI in their submission. If the Committee decides this is not the correct assessment then it can be changed here e.g. if the CPI has given a risk assessment of negligible or low risk and the committee has assess the risk as higher than that. The CPI will have to be informed of the change and requested to update the Project Details tab accordingly. The CPI's original assessment will be retained in the previous submitted forms and documents.

Approval decision date - You will then have to complete the fields regarding the approval decision (this is the date the committee approved the project not the date you are completing the information).

If this review assessment is from a subcommittee meeting then the fields below will not appear.

Approval expiry date – If the approval is from either Alternate Review or the HREC then you will need to enter the approval expiry date.

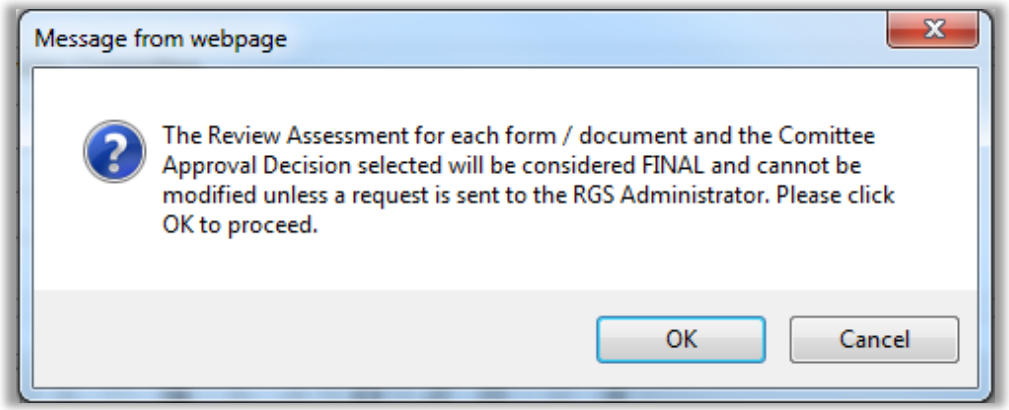
Progress report due date – the progress reports are usually provided annually but you can request them for a shorter period if the HREC has requested it from the CPI. The progress report is then required for each site on the same date regardless of when that site receives site authorisation.

Project specific conditions for approval - If there are any specific conditions that the Committee has decided that the project should be conducted under they should be entered in this field. These are not the standard conditions that each project is subject to but one that is specific to this project. An example of this would be is a waiver of consent is granted for the project. Entering the text of that specific condition or condition. This text will populate the letter and will also appear in the project workspace on the 'Summary' tab. The standard 'Conditions of Ethics Approval for a Research Project' that accompany the approval letter should not be entered here as they are already a part of the approval letter.

If all the information is not available when you first go to this screen you can press 'Save' and exit the screen. You can return to the 'Provide Review Assessment' screen at a later date to complete it.

Once all the information is completed, press the 'Finish' button.

This message will appear. Please make sure all information in the assessment is correct before proceeding.

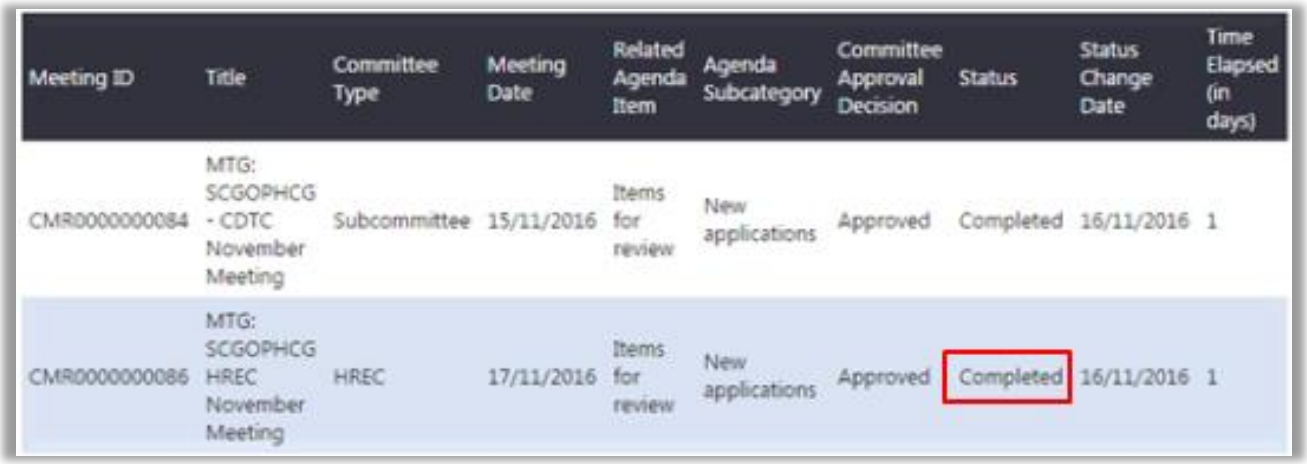


Click 'Okay' to finish or 'Cancel' to return to the assessment screen.

Note: Please remember to complete the Ethics tab, under Administration, to document components of your ethics review.

Please remember to complete the information under the Ethics tab related to the project. This information is required for various reports related to the project, the HREC and the organisation. You can go to the Ethics tab after you have finished with the review.

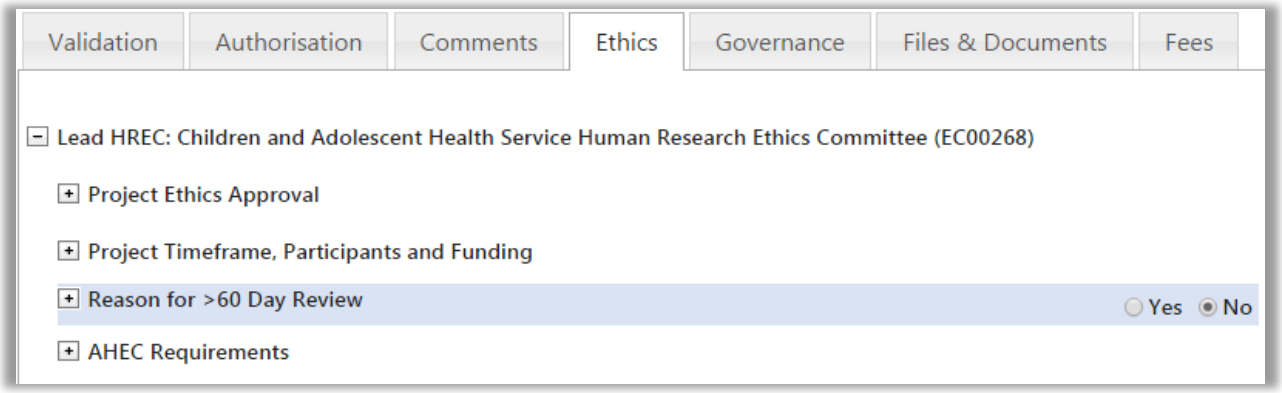
After you click 'Okay' you will be taken back to the Authorisation tab under the Administration tab. You will see that the meeting status is now completed.



Meeting ID	Title	Committee Type	Meeting Date	Related Agenda Item	Agenda Subcategory	Committee Approval Decision	Status	Status Change Date	Time Elapsed (in days)
CMR0000000084	MTG: SCGOPHCG - CDTC November Meeting	Subcommittee	15/11/2016	Items for review	New applications	Approved	Completed	16/11/2016	1
CMR0000000086	MTG: SCGOPHCG HREC November Meeting	HREC	17/11/2016	Items for review	New applications	Approved	Completed	16/11/2016	1

11.3 Complete the Ethics Tab

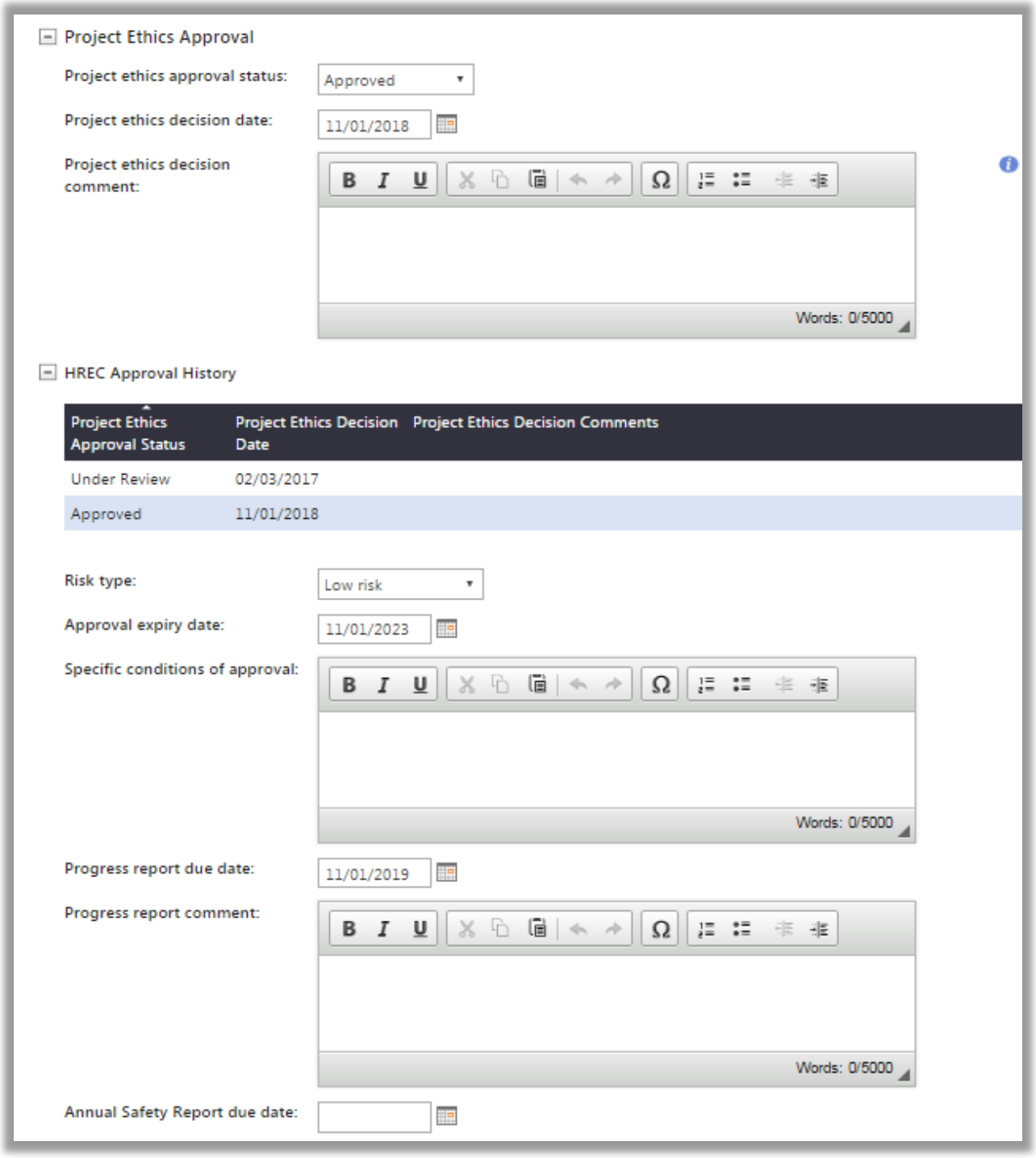
The Ethics tab contains information that is required for various state and national reports. It also is where the approval information is taken from to populate the project workspace. After you have completed the HREC's assessment of the project to either approved or not approved the information can be entered into this tab. Some of the information can be entered during the review process if it is available however it is an EEO's responsibility to ensure the information is entered for each project so that reporting requirements can be met.



There are four sections for each HREC as see above. Not all of the information will be available at the point of approval and there are no mandatory fields.

Project Ethics Approval

For the Project ethics approval status to be up dated in the Project Header you will need to complete the information in the first section Project Ethics Approval.



The following fields needs to be updated

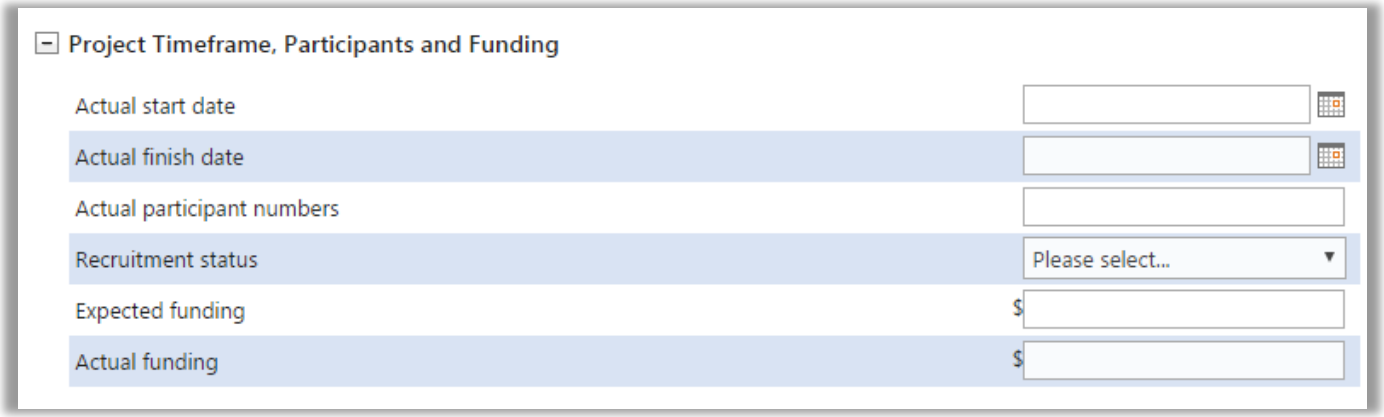
- Project ethics approval status this can be updated during the review process to Under Review and once the final decision has been made it can be updated to Approved or Not Approved. The HREC Approval History will show the changes.
- Project ethics decision date this is the date the decision was made not the date the review assessment was completed (e.g. the HREC meeting date, the HREC Ad Hoc meeting date or the Alternative Review meeting date).
- Project ethics decision comment this is for any general information about the project that you want other EEOs from your office to know about the project.

- Risk type: this is the risk type that the HREC has agreed on that might not be the same as the investigator had nominated.
- Approval expiry date needs to show the expiry date of the approval
- Specific conditions of approval this is not the general conditions of approval that are included in the approval letter, these are the conditions specific to this project, if a Waiver of Consent is granted for the project for some or all of the participants it should be detailed here.
- Progress report due date is the date the progress report is due. This is usually on the anniversary of the approval date but the HREC may have requested a shorter time frame for reporting.
- Progress report comment if a shorter time frame for the reporting is required the reasons can be documented here.
- Annual Safety Report due date is related to clinical trials and is the date that the report is due. This would be the reporting cycle of the trial and is unlikely to relate to the Progress Report date.

Remember to save regularly when entering this information.

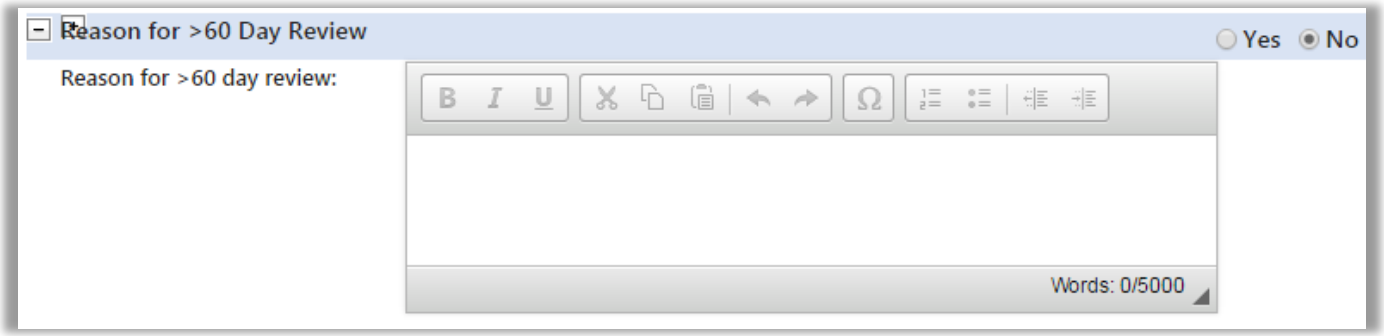
Project Timeframe, Participants and Funding

Apart from the expected funding (which will be in the WAHEAF, but not available if the HREA is used). This information will only be available as the as the project progresses and from the progress reports.



Reason for >60 Day Review

When a HREC review takes longer than 60 calendar days (with stop clock), the information can be entered in this field. This will then be available for reports. To enable this section click the circle next to the 'Yes'.



AHEC Requirements

The next section relates to the HREC that has approved (or not approved) the project. It includes the information that is required for reporting to AHEC. If both a Lead HREC and a Specialist HREC have reviewed project then each are given a section as each HREC will be required to provide their own report.

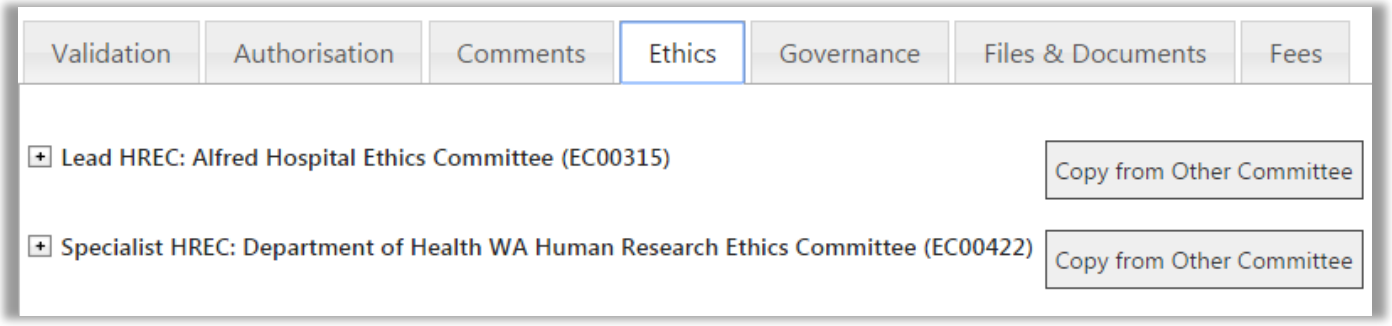
If any of the sections are relevant to the project you click the circle next to 'Yes'. The sections become active clicking on the plus sign will then expand the section. You can then enter the information related to that section.

11.4 Complete the Ethics Tab for External HREC

This section currently would only apply to the EEOs working for the Ethics Office that is associated with the Department of Health WA HREC.

The National Mutual Acceptance (NMA) means that sites within WA Health can accept the ethics approval of certified HRECs where their sponsoring institution is also part of NMA. This doesn't negate the need for Specialist HREC review if data linkage is involved in the project. If a project has both an External Lead HREC and Additional HREC (Specialist), then the EEO for the Specialist HREC will have to complete the information in the EEO tab related to the External HREC.

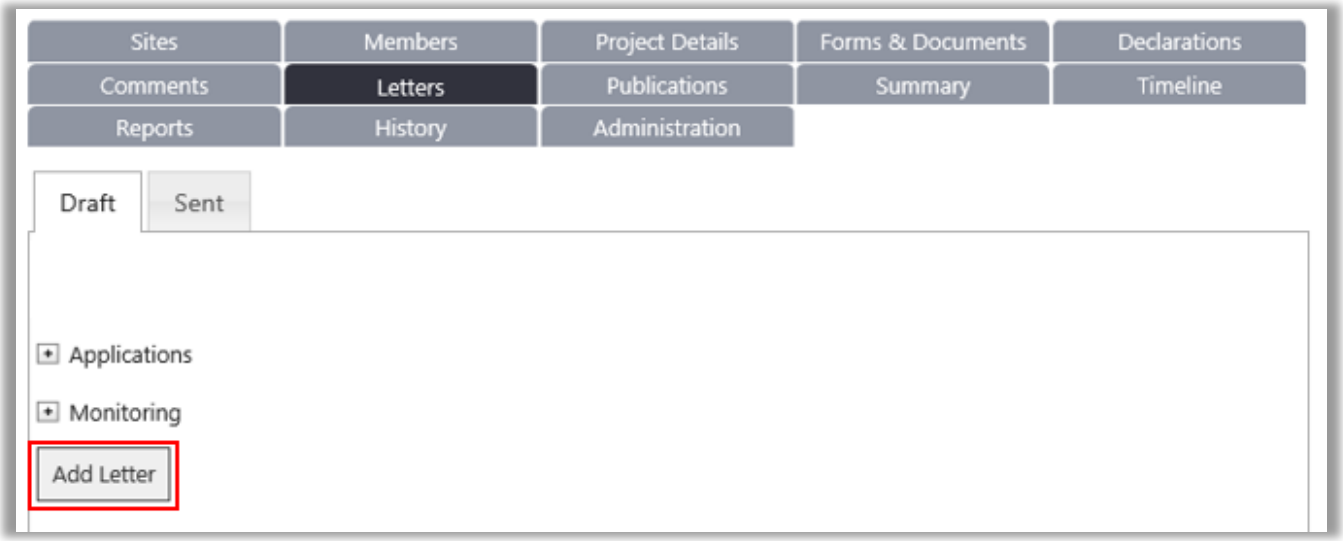
When you go to the Ethics tab you will see there are two HREC listed, these can be expanded by clicking on the plus sign next to the name.



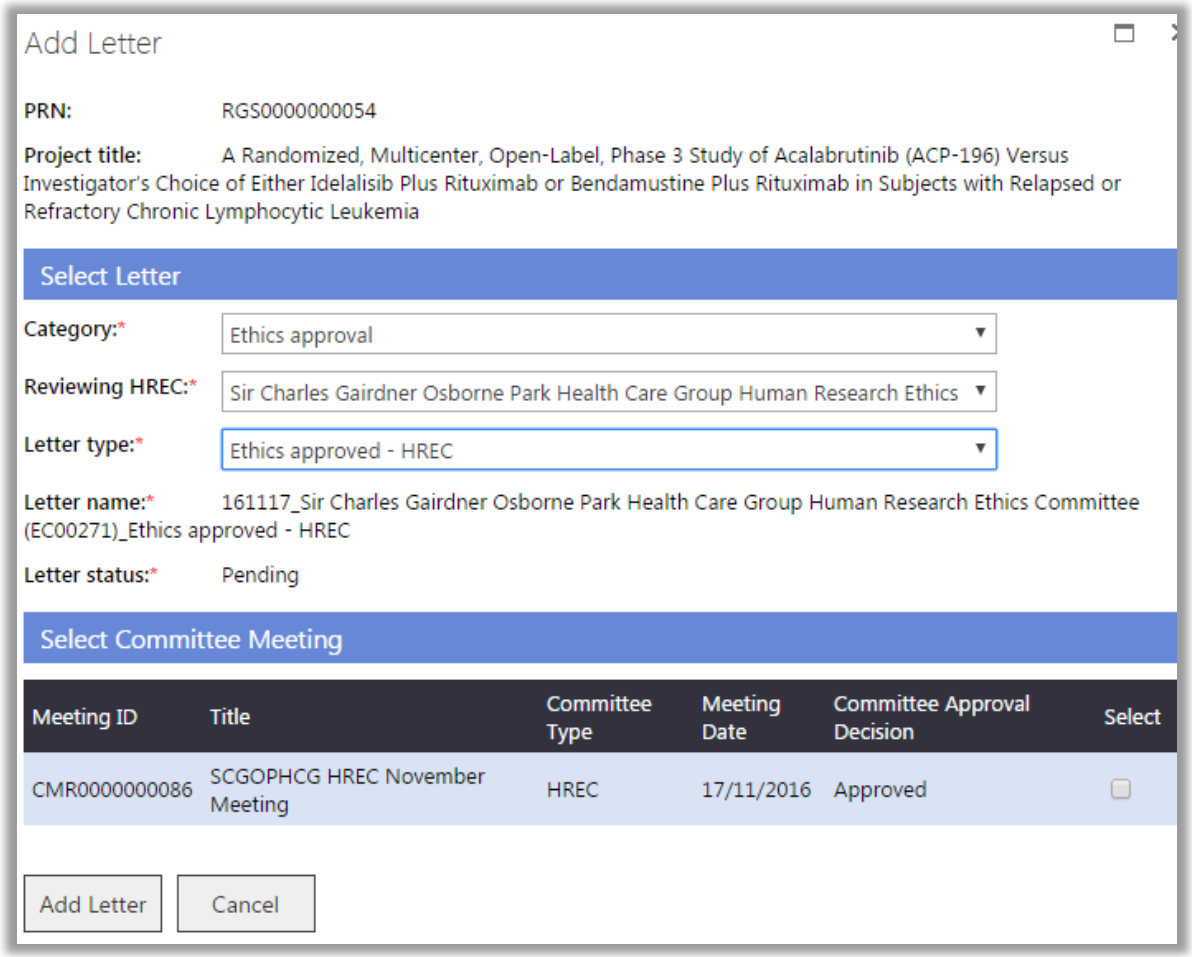
The external HREC doesn't have as much information as the WA Heath HRECs as there are no reporting requirements related to AHEC. The information should be in the HREC approval letter that is included with the submission. It is important to update this information so that it updates the Project Header and Summary pages. The Progress Reports date is always based on the Lead HREC approval date. The reason for this is so that the report is not based on different approval dates.

11.5 Letter to the CPI

Once the Review Assessment has been completed you can now create a letter to the CPI informing them of the committees review. Go to the letters tab and on the Draft tab press the 'Add Letter' button. You can create multiple letter from a single review assessment.



To generate a letter you need to complete the mandatory fields on the Add Letter screen. This screen is used by both EEOs and RGOs. The 'Category' of the letter will be ethics approval as all the letter templates associated to an ethics review are under this category. Once this is selected you will need to select the 'Reviewing HREC'.



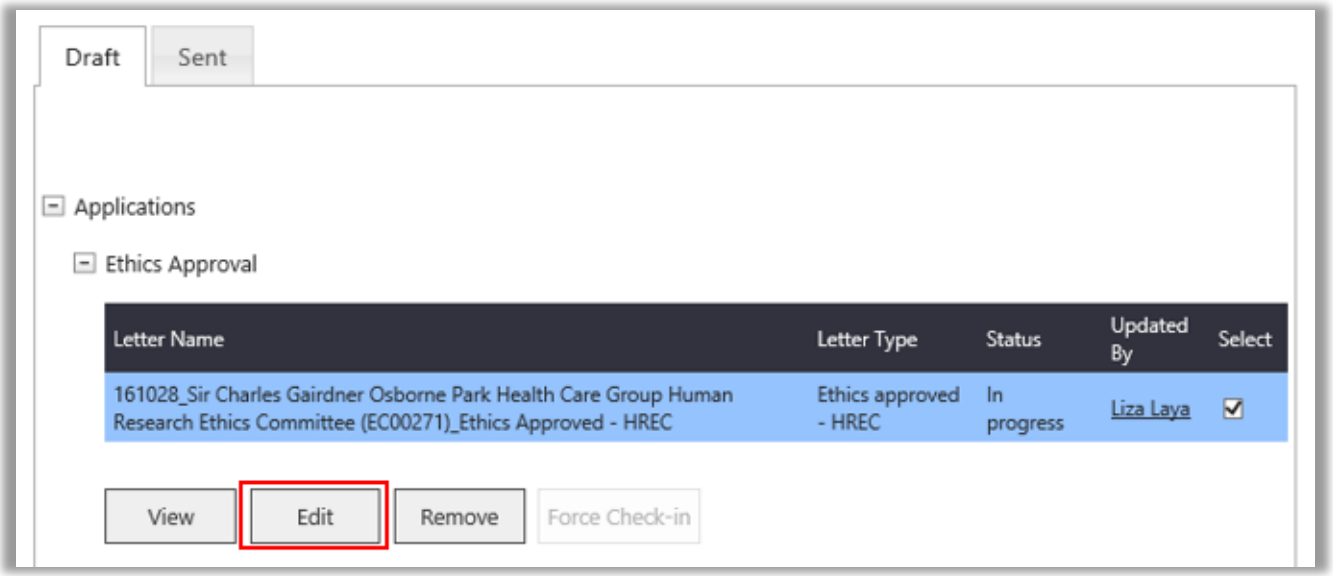
The 'Letter Type' will be dependent on the Committees decision. The options available are:

- **Ethics AIR – Alternative Review** – to be used if you are requesting additional information, from the CPI, as a result of the review conducted by the Alternative Review committee.

- **Ethics AIR – HREC** – to be used if you are requesting additional information, from the CPI, as a result of the review conducted by the HREC.
- **Ethics AIR – Subcommittee** – to be used if you are requesting additional information, from the CPI, as a result of the review conducted by the Subcommittee of the HREC.
- **Ethics approved – alternative review** – this letter is to notify the CPI that the project has been approved under the HREC alternative review, it will list the sites under the approval, the documents approved for use and if there are any special conditions specific to the project.
- **Ethics Approved – HREC** – this letter is to notify the CPI that the HREC approved of the project, the sites under the approval, the documents approved for use and if there are any special conditions specific to the project.
- **Ethics Approved – Subcommittee** – this letter is to notify the CPI that the subcommittee recommended the project and it has been forwarded to the HREC for review.
- **Ethics Not Approved – HREC** – this letter is to notify the CPI that the HREC has not approved the project and it cannot be resubmitted to the HREC for any future review.
- **Ethics not approved – Subcommittee** – this letter is to notify the CPI that the project has not been approved at a subcommittee level and it cannot be resubmitted again.

Select the most appropriate template, you cannot select a letter that is contrary to the Committees decision i.e. the Ethics Approved – HREC cannot be created if the Committees decision is AIR. Select the meeting the letter is related to and press 'Add Letter'.

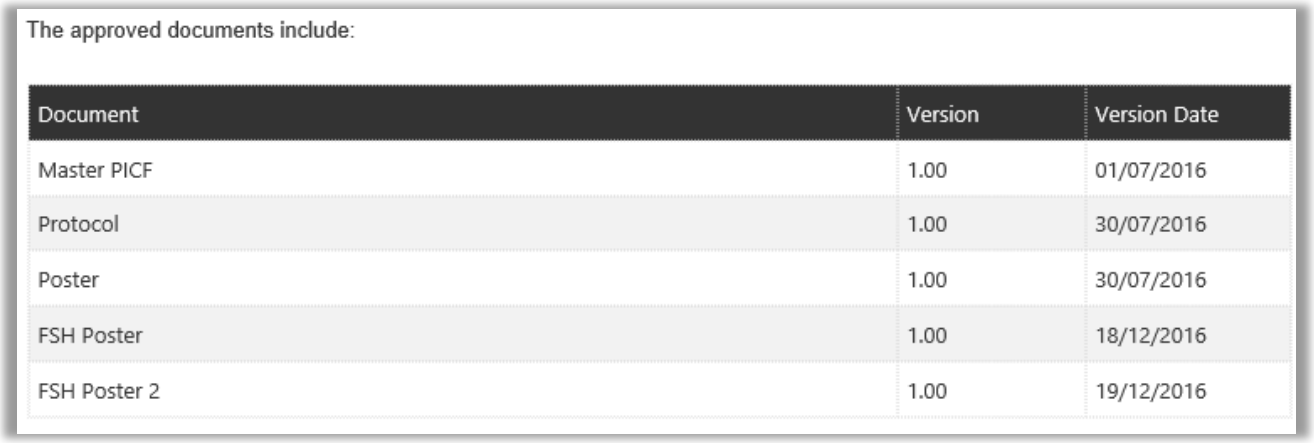
The 'Draft' tab is only visible to EEOs and RGOs. The letter you created is now in the 'Draft' tab tick the box under 'Select' and the 'View', 'Edit' and 'Remove' buttons will be enabled. If you click 'View' you will only see a preview of what the letter looks like. Click 'Edit' and you will be able to edit the content of the letter. Click 'Remove' to delete the letter, once deleted the letter cannot be recovered and a new letter will have to be created.



Clicking 'Edit' will bring up the draft letter. It has the same functionality as any text box in the RGS. You can also expand it using the triangle at the base of the box. Once the letter has been edited you can click 'Save & Close' the letter and you can go back and make further edits.

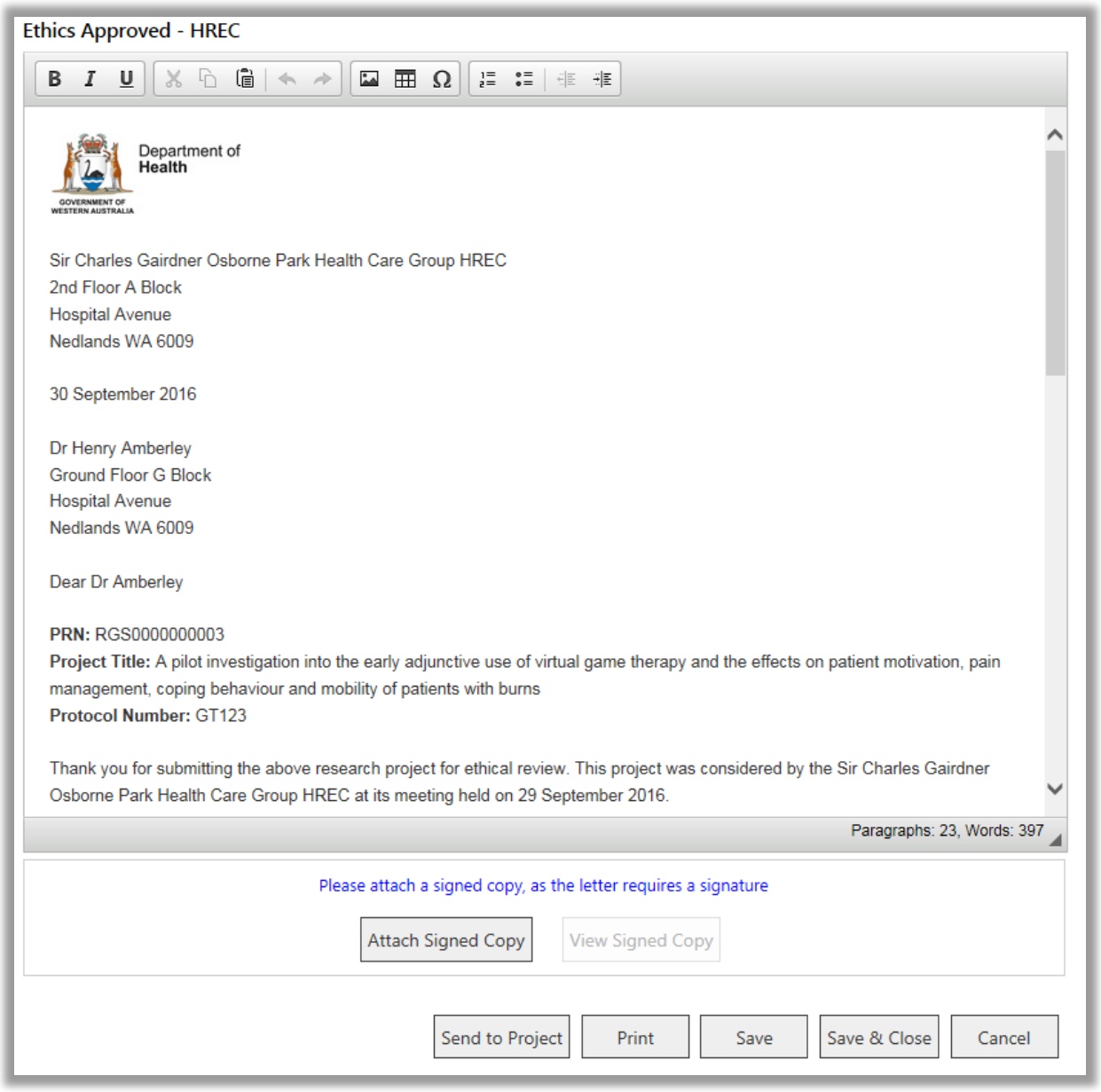
Remember to click 'Save' on a regular basis to ensure that any changes are saved. If you have made a change that you don't want to keep click 'Cancel' and it will close the letter and only retain the copy that you last saved.

If the letter is approving the project it will also list all the documents that have an approved status. The document name, version and version date are all taken from the information that the CPI/CPI Delegate provided when uploading the documents. This information is fully editable and if an approved document does not need to be listed (e.g. the HREA) then you can remove the row by right clicking in the row and in the pop up window select Row and delete.



The approved documents include:

Document	Version	Version Date
Master PICF	1.00	01/07/2016
Protocol	1.00	30/07/2016
Poster	1.00	30/07/2016
FSH Poster	1.00	18/12/2016
FSH Poster 2	1.00	19/12/2016



The following options are available by clicking on the following buttons:

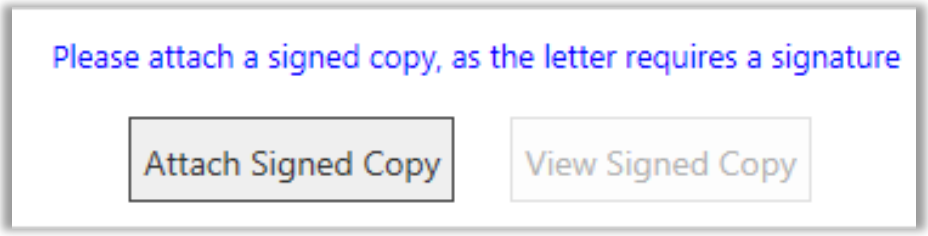
- **Send to Project** - this allows you to email the letter and the attachment (if applicable) to the CPI. It will move to the Sent tab and is no longer editable. Do not send it to the project yet if you also intend to attach a signed copy of the letter.
- **Print** - this allows you to print the letter and obtain a wet signature and then attach this signed copy to the draft letter. Select 'Print' and the letter will come up in a separate window.

  Right click and select 'Print' or 'Print Preview'. In print preview you can adjust the margins in the letter if required prior to printing Press the print icon which will give you the option of printers (if you have PDF software on your computer it will also give you that option). Once printed close the window.

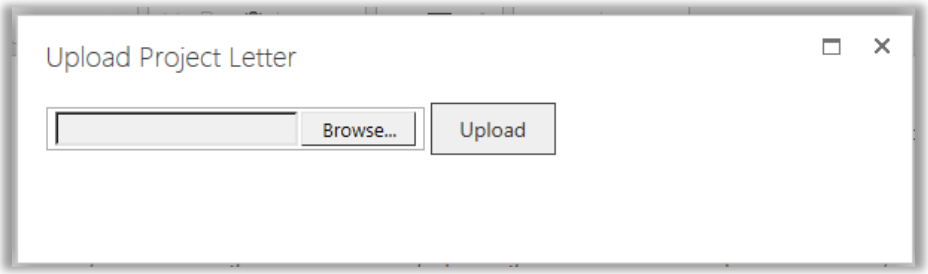
- **Save** - this saves any changes made to the letter during your editing. Remember to save frequently. Save & Close allows you to return to the letter later.
- **Cancel** - this discards any changes made to the letter.

Attach a Signed Copy

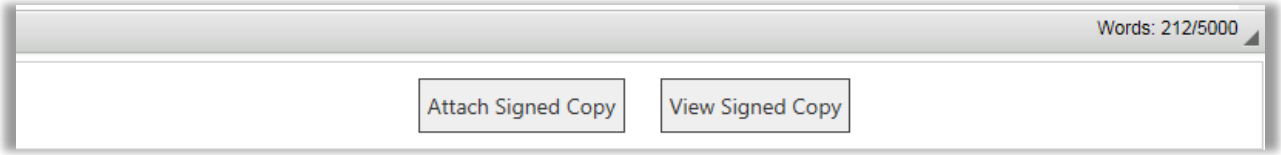
Click 'Attach Signed Copy' and the 'Upload Project Letter' launches.



Click 'Browse' to locate the document on your PC and the 'Upload' to attach it to the letter. Only PDF documents can be uploaded.

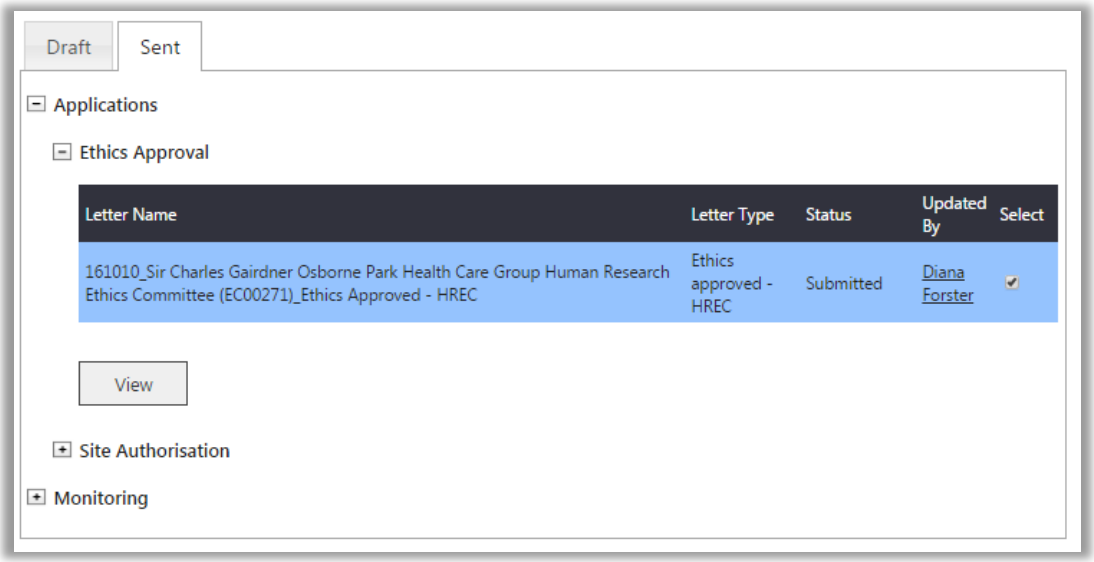


Once you have attached a document. The 'View Signed Copy' button is enabled and you can view the attached signed letter.



Click 'Send to Project' and the CPI will receive an email with the authorisation letter in the body of the email and the signed copy as an attachment. The letter is now in the Sent tab in the Letters tab. Project Members can select the letter and click 'View' to see it.

You can then view the signed copy to ensure it is correct. The last step is to click 'Send to Project' the CPI will receive an email with the approval letter in the body of the email. If there is a scanned copy of the letter this will also be attached to the email.

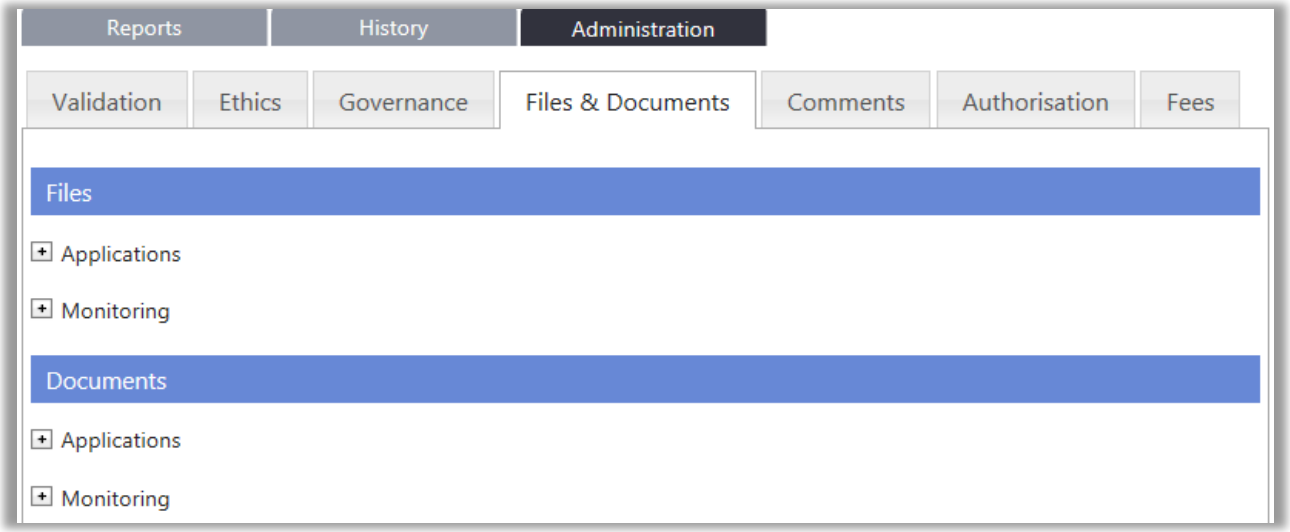


The letter is now available in the Sent tab (though this tab is labelled Received in the CPI's view).

12. Upload Files & Documents

To ensure all correspondence related to the project is saved in the one location, EEOs with access to the project workspace can upload documentation related to the ethics review e.g. email, in the 'Documents' section of the Files & Documents tab. If there is a hard copy file associated with the project, its location can also be recorded in the 'Files' section of the Files & Documents tab.

Note: EEOs also have the ability to attach documents in the Forms & Documents tab if they wanted to upload a document for the Project Members. Refer to Help Wiki: Upload supporting documents.

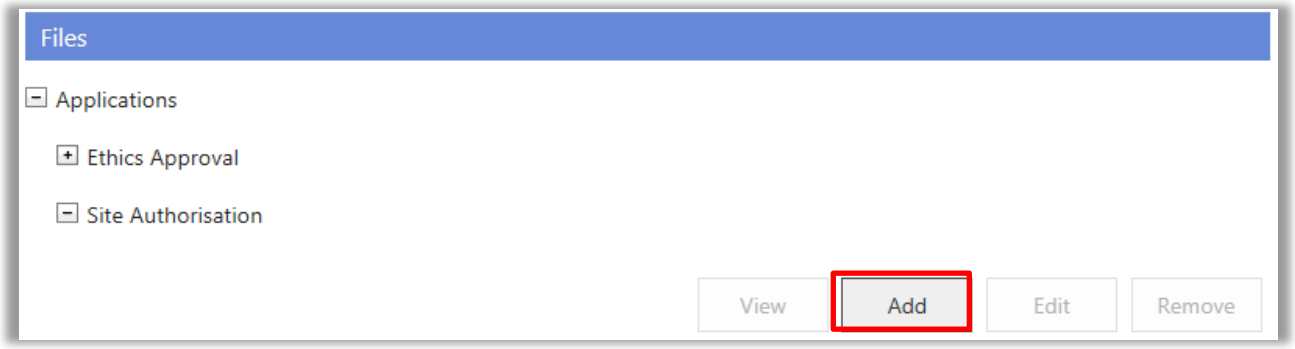


12.1 Files

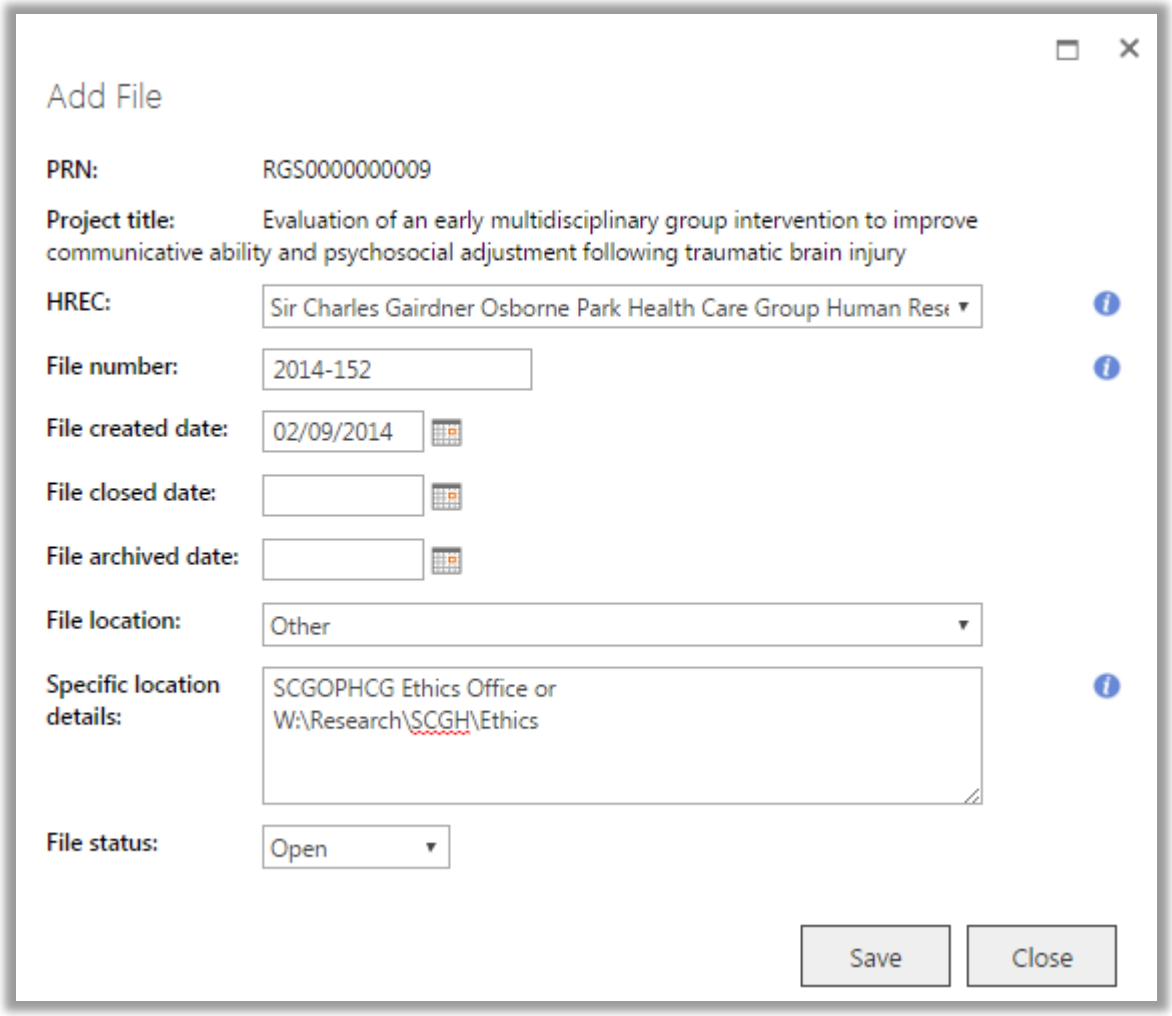
After the migration there will be a number of project that will be migrated that will still be active projects. If these projects have hardcopy or softcopy files their location can be entered into RGS for future reference.

In the project workspace, click on the Administration tab and then click on the Files & Documents tab.

In the Files section, click ‘Add’.

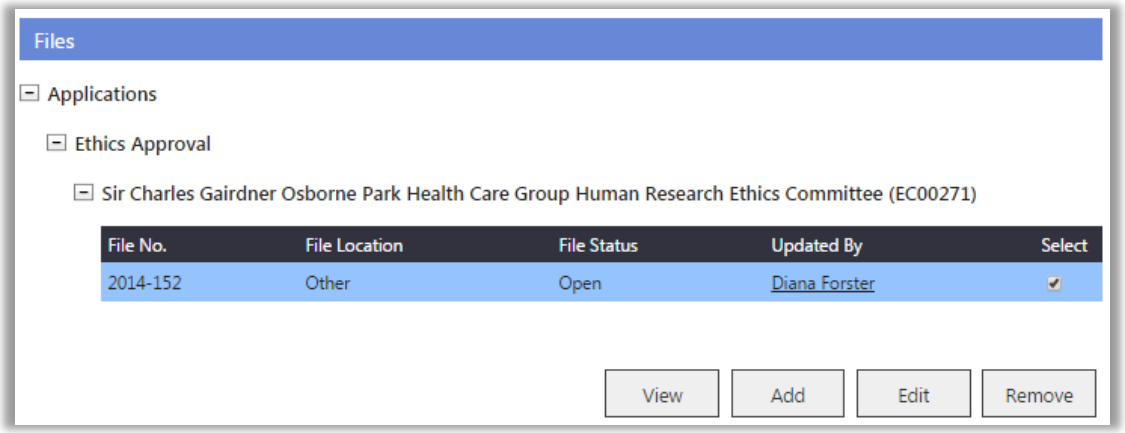


The ‘Add File’ screen will launch. Complete the details (refer to the tooltips provided) and click ‘Save’ to save changes or ‘Close’ to discard any changes made. If you select Other for the files location you can enter the Specific location details, this is where you can put the physical location if it is a hardcopy or if the documents are retained in softcopy the location of the folder can be added.



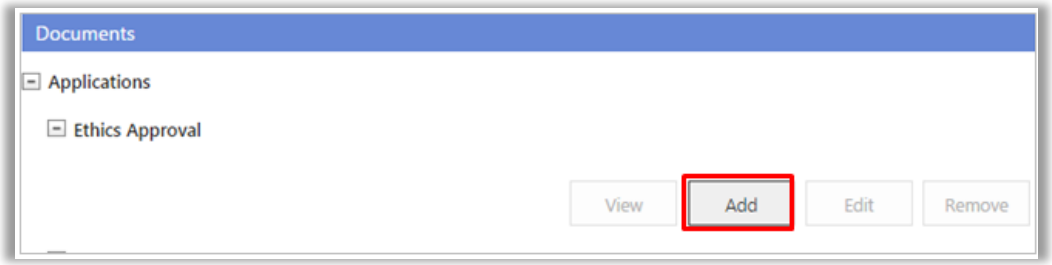
Note: If the file is kept at an off-site storage facility so you should also record its box number in case it needs to be retrieved at a future date.

The file location will be displayed against the associated site and Ethics Office. Once saved you can access the information by ticking the box under ‘Select’ and you can view, edit or remove.

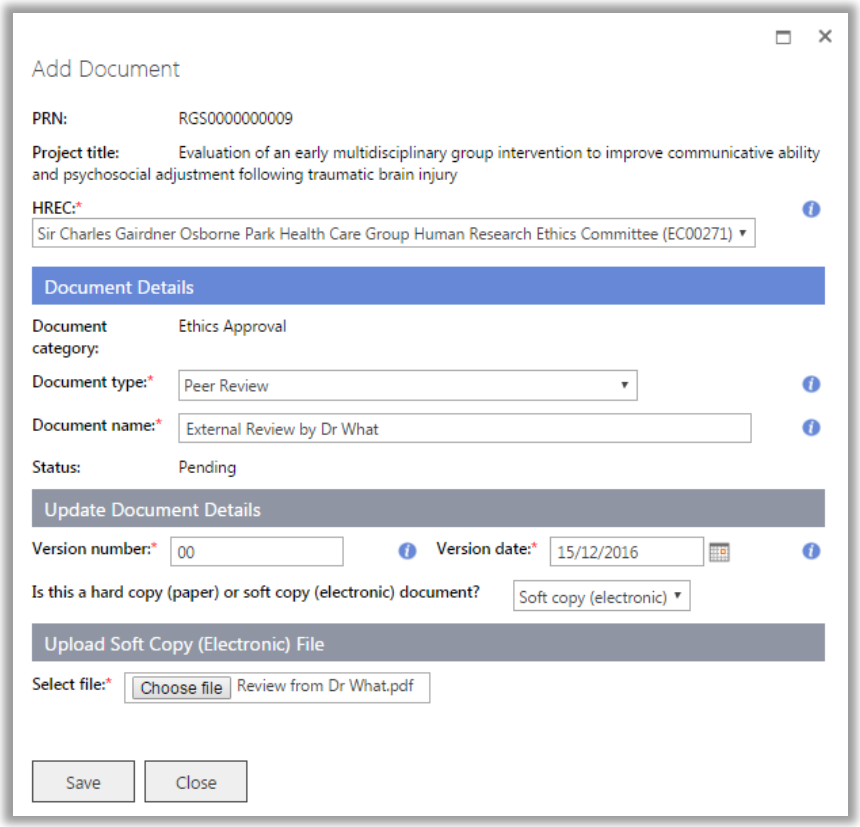


12.2 Documents

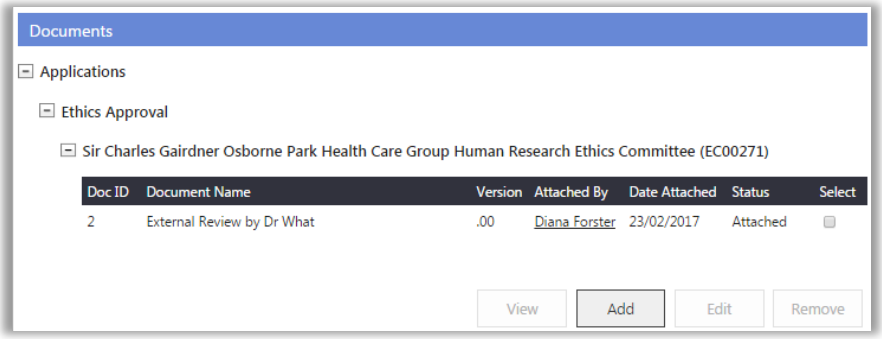
In the project workspace, click on the Administration tab and then click on the Files & Documents tab. In the Documents section, click ‘Add’.



The ‘Add Document’ screen will launch. Complete the details (refer to the tooltips provided) and click ‘Save’ to save changes or ‘Close’ to discard any changes made. You have the ability to nominate where a hard copy is located or upload a soft copy (e.g. external review from requested by the HREC).



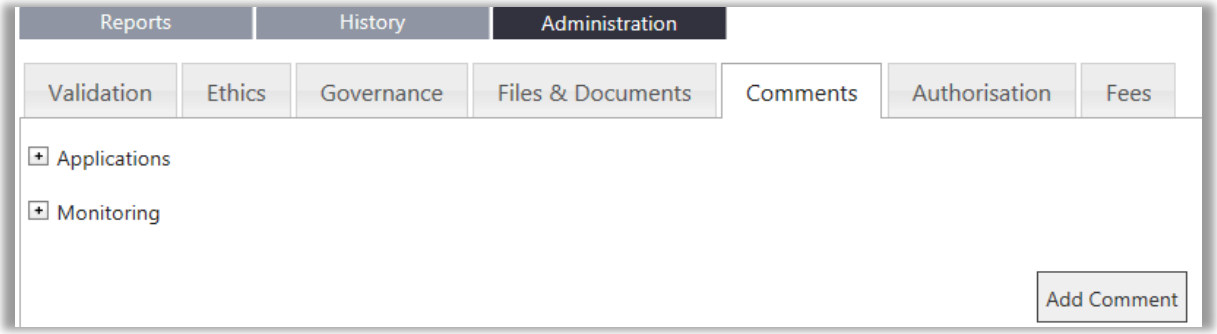
The document will be displayed against the associated site and Ethics Office. Select the document to view, edit or remove.



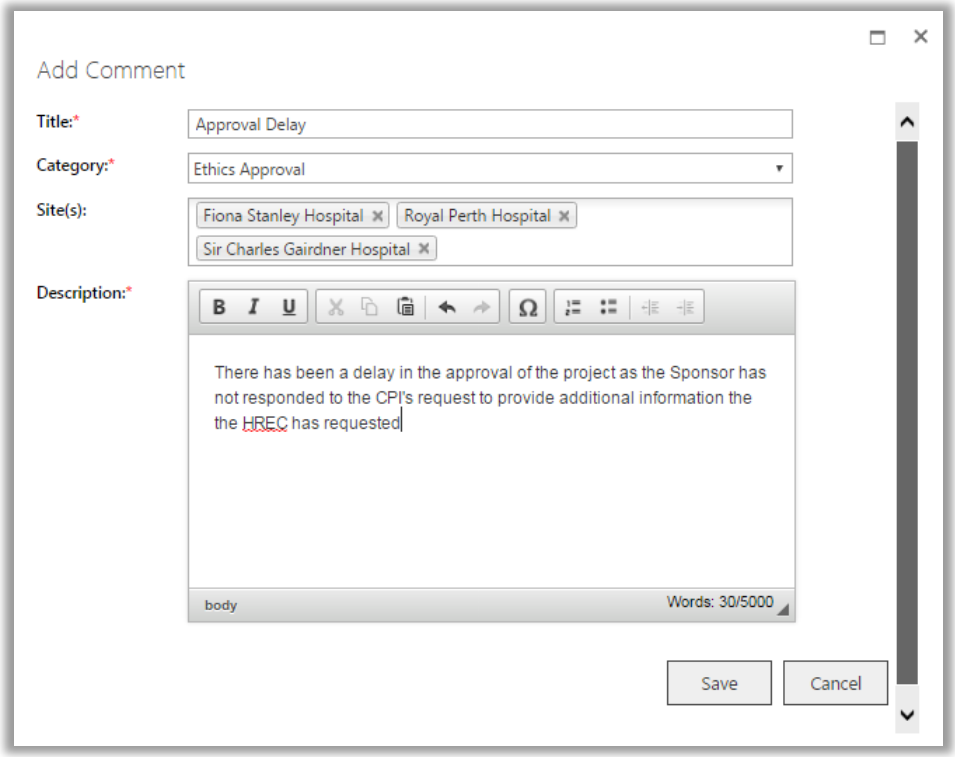
13. Add a Comment

EEOs within an Ethics Office have the ability to post comments on the project that are only visible to EEOs within their office and the RGS Administrator.

In the project workspace, click on the Administration tab and then click on the Comments tab. Click ‘Add Comment’.



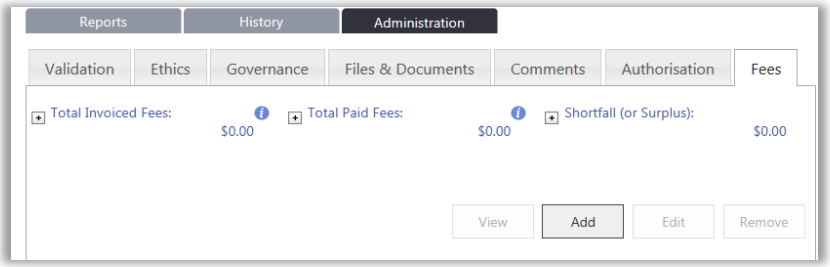
The ‘Add Comment’ screen will launch. Complete the details (refer to the tooltips provided) and click ‘Save’ to save changes or ‘Cancel’ to discard any changes made.



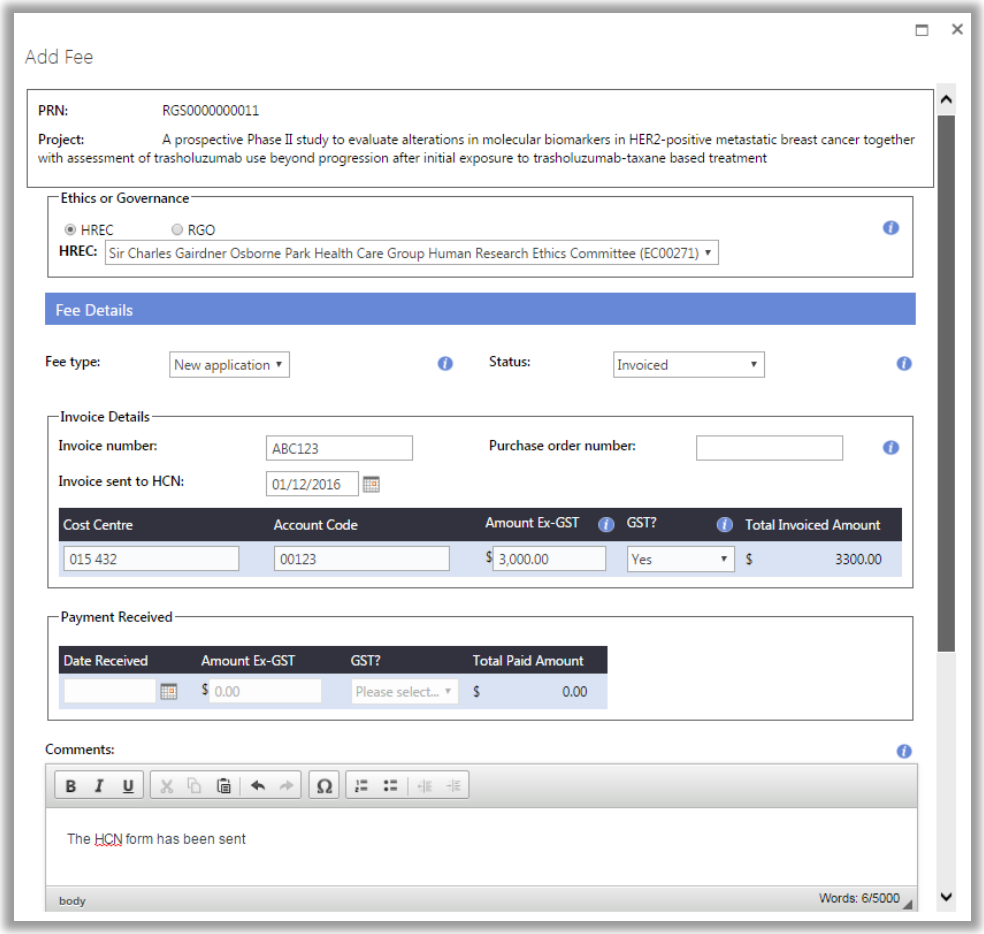
The comment will be displayed against the associated site and Ethics Office. The RGS Administrator has the ability to remove any inappropriate comments. To remove a comment, click the 'red cross'.

14. Manage Fees

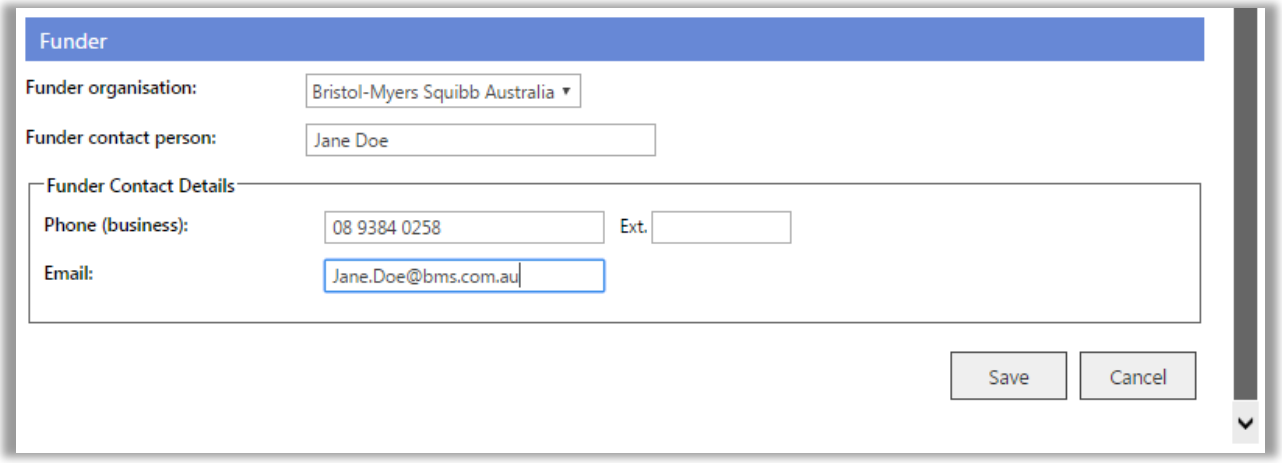
The Ethics Offices can manage fees related to the committee's review in the Fees tab. In the project workspace, click on the Administration tab and then click on the Fees tab. Click 'Add'.



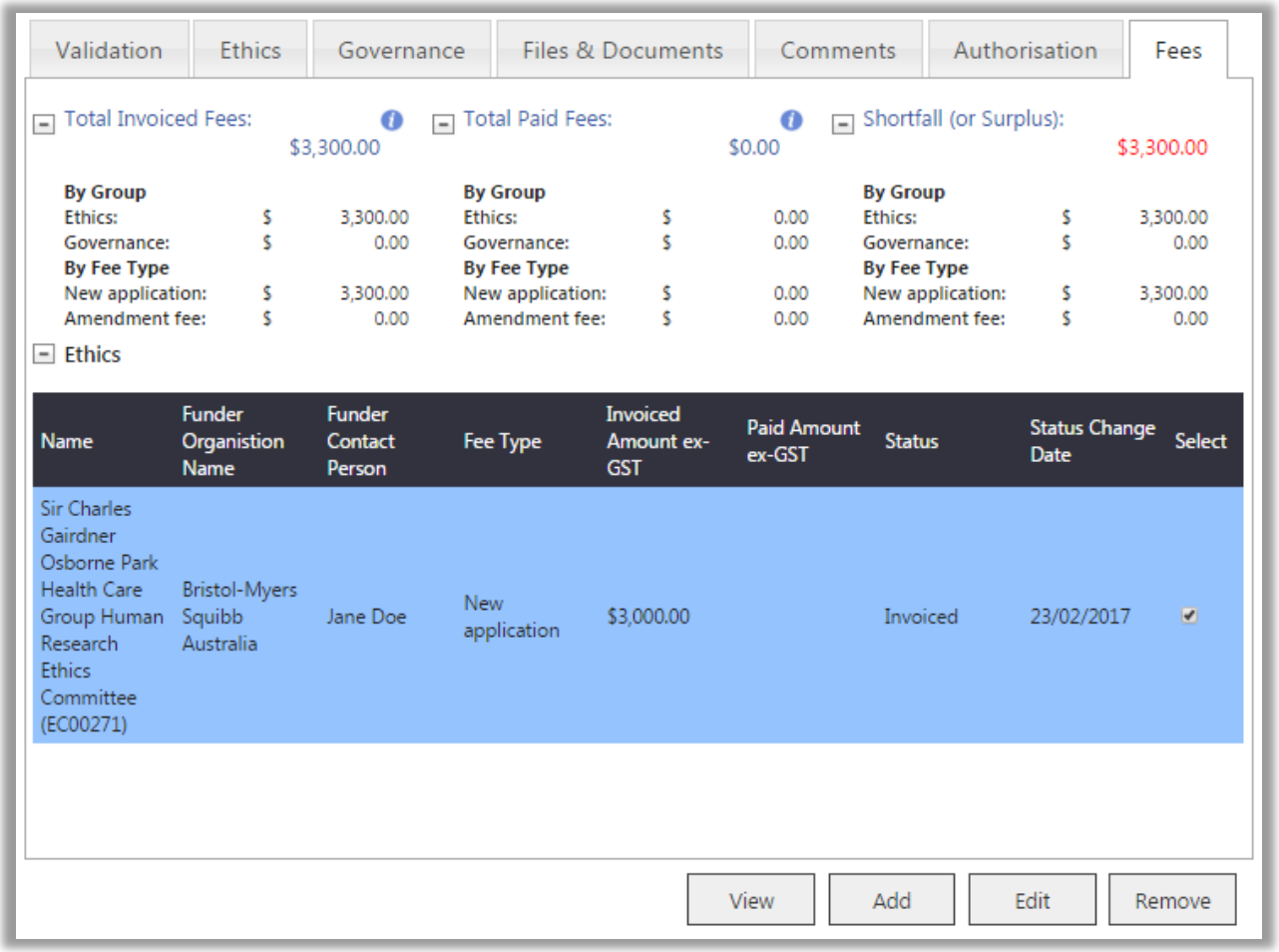
The 'Add fee' screen will launch. Select 'HREC' and the committee name, then Fee type (new application or amendment) and Status. The status chosen will affect the remainder of the sections that should be completed, this should be updated as required (e.g. when a payment is received). Complete the remaining 'Fee Details' (refer to the tooltips provided).



Scroll down the screen and complete the ‘Funder Details’. Select the funder (i.e. from the funders nominated in Project Details) and enter their contact details. Click ‘Save’ to save changes or ‘Cancel’ to discard any changes made.



The details regarding ‘Total Invoiced Fees’ and ‘Total Paid Fees’ will be displayed in the Fees tab. Select a ‘Ethics’ fee to either view, edit or remove it.



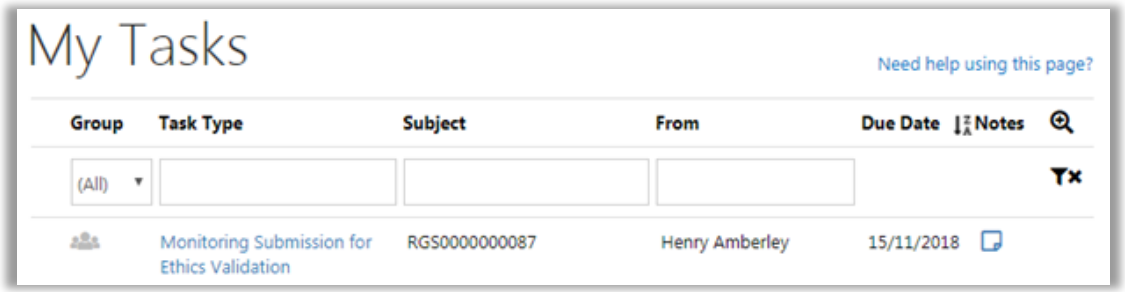
15. Monitoring (post approval)

The workflow for monitoring forms and documents is the same as for site authorisation. The Monitoring tab has a different layout. The forms and documents for both the HREC and the RG Offices are in the same place. For more information see the Help Wiki pages linked in the list below.

The types of monitoring forms are

- Amendment
- Governance Only Amendment
- Safety Report
- Progress Report
- Site Final Report
- Project Final Report

All monitoring submissions generate tasks.



The validation process for monitoring is the same as applications, however all completed validations and review assessments are not visible unless you tick 'View All Records'.

15.1 Adding monitoring submission to a meeting

Adding a monitoring submission to a meeting is the same as for application only it is done under the Monitoring section of the Authorisation tab.

If you add two monitoring forms from the same project to the same meeting once you have validated the second submission, go to the calendar and select the meeting and add the submission from the agenda.

15.1 Items Approved Out Of Session

The monitoring workflow has an additional process; it can be reviewed and approved out of session without the need to create an Ad hoc or Alternative Review meeting. The submission is still validated. If during validation you decide the submission can be reviewed out of session, you can complete validation (reviewing the form and document(s) at the same time. The submission can be added to the next scheduled meeting under Items Approved Out of Session.

Sir Charles Gairdner Osborne Park Health Care Group Human Research Ethics Committee (EC00271)

View All Records

Meeting ID	Title	Committee Type	Meeting Date	Related Agenda Item	Agenda Subcategory	Committee Approval Decision	Status	Review Completion Date	Time Elapsed (in days)
CMR0000003193	MTG: SCOPHCG HREC August Meeting	HREC	17/08/2018	Items approved out of session	Monitoring - Amendments	Approved	Completed	03/08/2018	0
CMR0000004234	MTG: SCGOPHCG HREC November Meeting	HREC	20/11/2018	Items approved out of session	Monitoring - Amendments	Approved	Completed	12/11/2018	0

Once it is added the form and all attached document will have the status of approved. The letter for the submission then has to be created. The Ethics tab should always be updated before any letters are created. If the submission was the Progress Report, or for the extension of the approval expiry date, the appropriate field should be updated before the letter is created.

15.2 Amendment Forms

There are two types of amendment forms, the Amendment Form and the Governance Only Amendment Form. The Amendment Form can be submitted to both the HREC and RG Office (if there are no site specific documents related to the changes). The Governance Only Amendment (GOA) Form is used when the changes are site specific. The Amendment Form can't be sent to the RG Office until it is approved by the HREC, nor is it available to be attached to the GOA Form until it has been approved by the HREC.

15.3 Safety Report

The safety report is used to report to either the HREC or RG Office any safety issue. This form is not used to report a safety issue to a HREC outside WA Health, the reporting format that the HREC has prescribed must be used. The form can be used to report the following:

- Serious Breach
- Significant Safety Issues (SSI)
- Sudden Unexpected Serious Adverse Reactions (SUSAR) or Unanticipated Serious Adverse Device Effect (USADE)
- Annual Safety Report and/or Updated Investigator Brochure

This form can be submitted to either the HREC, RG Office(s) or both depending on what is being reported. Due to the possible urgency of the report, if they are submitted to both the HREC and the RG Office each can process the report at the same time. It is the CPI's responsibility to inform each site of the outcome of any safety report submission. After the

review of the report and the letter is created and sent to the CPI, all project members will be able to view the letter.

15.4 Progress Report

The minimum monitoring requirements for both HRECs and Research Governance are the submission of a progress report annually. A HREC can request that a progress report is submitted more regularly than annually. Both the Ethics and Governance tab have a progress report due date, this is usually set on the anniversary date of the HREC approval so that only one report has to be created and submitted, however if a condition of approval is that this progress report is to be submitted more frequently, this date should be entered into the Progress report due date field. The CPI and CPI Delegate will receive a reminder at a month and a week prior to the report due date.

The progress report form can be submitted to the HREC and RG Office(s) at the same time and the review process for HREC and the RG Offices are independent of each other. Once the form has been reviewed and approved the Ethics tab should be updated with the new progress report due date before the letter is created.

15.5 Final Reports

There are two types of final reports. A Site Final Report is used to close the project at a WA Health site. Each site in a project has to be closed before the project itself can be closed, the Project Final Report is not submitted until each WA Health site has been closed. The RG Office does not receive the Project Final Report. Non WA Health site/s closures information are included in the Project Final Report.

The Project Final Report is also completed if the project closed prior to the expected completion date. The form is submitted to the Lead HREC and the Specialist HREC (if applicable). When the form has been review and approved and the Ethics tab updated the letter should be created.