This guide is provided for Macquarie University’s Human Ethics Secretary and Subcommittee Administrators

Version 1.2

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Human Ethics Application Form

From March 2014, Macquarie University’s human ethics application forms will be transitioning to online forms. This will be accessible through the Integrated Research Information System (IRIS) website using the Research Master Online Network (RMENET).

By logging in to IRIS (using your MQ OneID and password), you will be able to assign reviewers and manage applications utilising the Human Ethics Application Form.

This user guide will help you to log in, manage the review process, attach approval letters, and enter key administrative information for each human ethics application submitted by researchers to MQ’s Human Research Ethics Committees (HRECs) and Ethics Subcommittees.

There are seven (7) key steps for each application – for your convenience, these are numbered in chronological order throughout this user guide.

Browser compatibility

The MQ online forms are most compatible with Mozilla Firefox (any version). Other browser options include Google Chrome (any version), Apple Safari (for iPads only – versions 4 and 5), as well as recent versions of Internet Explorer.

Getting Help

If you do not have a ‘OneID’, please contact:

Web: Sponsored OneID request
Phone: +61 2 9850 4357

For login issues, please contact:

Web: IRIS Login issues
Phone: +61 2 9850 4357

To report a problem with the online form:

Web: Report to OneHelp
Phone: +61 2 9850 4459

For questions regarding the online form:

Web: Frequently Asked Questions
Web: OneHelp Inquiries
Phone: +61 2 9850 4459

To discuss issues specific to your human ethics application, please contact:

Email: ethics.secretariat@mq.edu.au
Phone: +61 2 9850 4459

For all other technical assistance, please contact OneHelp:

Web: OneHelp website
Email: help@mq.edu.au
Phone: +61 2 9850 4357

Note: You may also want to check the time and date of the next available training.
Who will be using this form?
With all staff and students of Macquarie University (MQ) and Macquarie University Hospital (MUH) adopting the IRIS application form throughout 2014, all ethical review involving MQ's Human Research Ethics Committees (HRECs) and Ethics Subcommittees will soon take place using this online system.

What forms are being replaced?
Researchers and research students completing a new ethics application will need to use the online Human Ethics Application Form (not the Microsoft Word version).
Applicants who already have current ethics approval from an external HREC where all of the research will be conducted offsite (External Review) or where ethical review is being sought for additional sites (Prior Review) will also need to use the online Human Ethics Application Form.
Please refer to the Online Forms Project page to view the relevant launch dates.

Any tips before I start?
1. In your browser preferences, allow pop-up windows for the IRIS website (i.e. https://iris.mq.edu.au/rmenet)
2. If and when you are offered the option to "Prevent this page from creating additional dialogs" (see below), please ignore and do not tick the checkbox.
1. Logging in and locating an application

When a new application has been allocated to a committee, the system will automatically send an email to the shared administrator address for that committee (e.g. ethics_secretariat@mq.edu.au).

In the first line of the email, the text will make reference to the Application ID number (e.g. 5201401234), the surname of the Primary contact in the application, and the Ethics Application Title. This will help you locate the application in your list once you are logged in.

Logging in

To log in, go to the IRIS website (https://iris.mq.edu.au/RMENet/) and enter your MQ OneID User Name and Password.

Locating: Applications

Once you have logged in, the home screen will appear. Select Ethics >> Applications from the main commands across the top (as shown below).

Select For Assessment Review (if it has not already been selected) to locate all the applications requiring review – these will be listed in the table. However, if all the reviewers assigned to this application have each lodged a decision, then the application should be accessible via the All Applications heading.¹

¹ If you are not nominated as the committee secretary in the IRIS database and need to access applications for a particular committee, please contact the Ethics Administrator in the Research Office via (+61 2 9850 4459 or ethics_secretariat@mq.edu.au).
Locating: Managing Applications

Alternatively – particularly if the list of applications is long – you may choose to find the application by selecting Ethics >> Manage Applications from the main commands across the top.

1. First, select the ‘+’ symbol next to Filter your Applications to open up the options.
2. Select the radio button next to All Applications to open the advanced search.
3. Enter your search criteria (Application ID is recommended).
4. Click ‘Search’.

Locating: External Review – Research Office only

All External Review applications will appear under Ethics >> Applications >> For Review (as shown below).
Navigating each application

Once the application is created or opened, you will be presented with several window panes and icons as shown below.

Layout and navigational panes:

1. **Top-left pane:** Title and Status bar
   This area lists the current formal title of the project, the current application status and workflow state, as well as other Human Ethics forms currently available.

2. **Left-hand side pane:** Form and Action menus
   This pane lists the various sections and pages of the application form under the “Form” tab. The “Action” tab lists the options currently available to the user (e.g. Submit application).

3. **Top-right pane:** Icon menu
   This pane contains important navigational icons, available throughout the application (e.g. Next Page, Previous Page, Save, etc.).

4. **Main pane:** Current page
   This pane shows the content of the current page selected in the form.

The details for each of these panes are discussed in the next section.
1. Top-left pane

This pane displays three (3) key features:

1. Application title
   This displays the current title as displayed in question 1.1, "What is the formal title of this research proposal?"

2. Application status
   This displays information that describes the progress of the application to date.
   This status will continue to change throughout the application process. Some examples include:
   - HREC Review (under review by HREC)
   - Subcommittee Review
   - Scientific Review
   - Additional Information Requested
   - Resubmission
   - Redraft (significant revisions required)

3. Workflow state
   This displays information that describes who is currently editing or reviewing the application. To some extent, it also reflects the progress of the application.
   Some examples include:
   - Secretariat
   - HREC (HUM)
   - HREC (MDS)
   - Subcommittees
   - MGSM
2. Left-hand side pane

There are three (3) tabs visible in this pane:

1. Form
This contains the hyperlink index to each section of the application form.

There are also options to “Expand” or “Collapse” the list of pages in the form.

A yellow triangle ( › ) marks each page that is yet to be viewed by any party.

When all mandatory questions on a page are completed, this icon will change into a green tick ( ✓ ) once the “Save” icon is selected or once you have navigated to another page.

2. Review
This contains the following links:
- <Name of committee/process state>: where to assign and remove reviewers
- Reviewer Assignment History: provides a list of previous and current reviewers for the application; functions for notifying reviewers
- Review Outcome: allows you to view the history of individual decisions made by previous and current reviewers

3. Action
This will include some combination of the following links:
- Reassign to HREC
- Forward to HREC [Scientific state only]
- Reassign to Subcommittee [HREC states only]
- Reassign to Scientific [HREC states only]
- Reminder
- Request additional information
- External Approval Noted [Secretariat state only]
- Approve application
- Reject application
- Meeting state [HREC states only]
3. Top-right pane

The help and navigational icons are as follows (from left to right):

- Previous Page
- Next Page
- Save
- Application Comments
- Reports
- Page Comments
- Page Help
- Exit

4. Main pane

This main pane displays the content of the current page selected in the form. You may click on any of the active links without navigating away from the form.

Asterisk

Any field marked with a red asterisk (*) is a mandatory field and must be completed before the application can progress.

Help Icon

Question help is available for many questions throughout the application by clicking the blue question mark icon. To close the help text, click on the close symbol (X).

Previous and Next Page icons

Selecting these icons will take you to either the previous page or the next page. These icons will also automatically save the current content.

Confirm and Cancel icons

The Confirm (✓) and Cancel (X) icons also appear for table questions (i.e. Personnel, Attachments and Signoff) as well as entering comments.
2. Reviewing applications and attachments

Reports

While looking at an application, go to the top right-hand pane and **click on the Reports icon** (binder picture).

Select ‘Ethics Application’ (default option), choose from PDF or HTML, and **press ‘OK’**.

This will allow you to review the entire application at once.

Depending on your machine’s preferences, this file may open in a new browser tab/window titled *Printer Friendly Version* or in Adobe Reader (PDF only).

**Note:** You may want to keep this Report open while assigning reviewers.

To close the *Printer Friendly Version* box, select ‘Cancel’ or the ‘X’ symbol at the top-right of the dialogue box.

You may repeat the same process to view the ‘Attached Documents’ as a report. Alternatively, attachments can also be accessed via the *Attachments* section in the *Form* tab.
3. Admin only section

Notifications (all applications)

Once an application is submitted by the applicant(s), the system is programmed to generate a number of notifications – intended for the committee secretary – in relation to certain responses throughout the form.

These notifications cannot be viewed via the Reports function and must be accessed through the ‘Admin only’ page in the Form tab (in the section of the same name).

To access the notifications, navigate to the Admin only section (near the bottom of the Form tab) and select the ‘Admin only’ page.

Each notification will appear in the main pane of the screen above question 12.1.

Linked applications

This notification alerts the committee secretary to connect the current application to a previous application listed in the database – based on the responses given by the applicant(s) at questions 1.2, 1.2.1 and 1.2.2.

Note: You will have to answer question 12.3 (“Current committee providing review”) first before navigating to any other page.

Navigate to the ‘Title’ page in section 1. Key aspects) and review the answers at 1.2, 1.2.1 and 1.2.2.
Linked applications (continued)

Copy the information provided by the applicant(s) at question 1.2.2 (e.g. highlight and copy with your mouse) and navigate to back to ‘Linked applications’ page in the Admin only section.

At question 12.5, enter the search criteria into the textbox (and click on the magnifying glass) or select “More Criteria” for an advanced search – allowing you to search investigator and/or ethics application status.

Once the search is complete and the application has been selected, the table will expand to display the details of the previous application (e.g. Title, Application status, Department, etc.).

If this is the correct application, select the green tick; if incorrect, select the red cross and search again.

Once the correct entry is confirmed, this will appear in the table.

To save the changes, select the Save icon or simply navigate to another page – this will be confirmed by with a green tick appearing next to the Linked applications page in the Form tab.
Conflict of interest declared

When a process-related conflict of interest (COI) is declared in the Signoff section – by the applicant(s) and/or the signoff party (i.e. Head of Department) – a corresponding notification is displayed on the ‘Admin only’ page.

**Note:** You will need to refer to the relevant page(s) in the Signoff section to determine if any action is required.

When a declaration is made by the applicant(s), the committee secretary is asked to select the most appropriate statement from the drop-down list – the default option being “No conflict with HRECs and Subcommittees”.

Your answer here will assist all ethics administrative staff with determining appropriate reviewers.

When a declaration is made by the signoff party, you may need to consider:

- Reassigning a more appropriate signoff party (via the Ethics Administrator in the Research Office), or
- Ensuring that the signoff party does not also participate in the review of the application as a committee member.

Fee – HREC applications only

Any application where the project is funded by a sponsor or the primary contact is an external applicant will involve a fee. Please process an invoice as required before ethical review commences.

Check responses

Where it is indicated by the applicant(s) that the research data will not be retained for the minimum period (i.e. five years), the system will alert the committee secretary to check this response in section 8. Privacy & confidentiality.

Likewise, if one or more requested attachments are not present in the Attachments section, the system will ask the committee secretary to check the ‘Documentation’ page.

This will contain the reasons given by the applicant(s) regarding why the application was submitted without this material.
**Children under five – HREC applications only**

When a project intends to involve children less than five years of age as participants, the applicants are required to notify the university’s insurer before submission and to indicate that this has taken place in the Signoff section.

Once such applications are available for ethical review by a HREC, the committee secretary will be asked to identify if the research is “Greater-than-low risk” or “Low risk” (question 12.0c).

![Question 12.0c]

When “Low risk” is selected, no further action is required.

When “Greater-than-low risk” is selected, this will prevent the application from being sent to an Ethics Subcommittee. At this point, it is advisable that you liaise with the University’s Tax and Insurance Officer (Ms Maggie Feng): (p) +61 2 9850 1683 (e) maggie.feng@mq.edu.au.

**Override applied by Ethics Administrator**

In the event that the Ethics Administrator (i.e. in the Research Office) has intervened in triaging an application, the following message will appear at the top of the ‘Admin only’ page:

![Admin only]

As some of the override functions may intervene with other actions (e.g. reassigning to another committee), this message is displayed as a reminder. Should you experience any issues while this message is displayed, please contact the Ethics Secretariat to speak with the Ethics Administrator.

**General notifications – no action required**

The following general notifications are also displayed on the ‘Admin only’ page to assist with processing certain types of applications:

- This is a Prior Review application.
- This is a Multi-site Review application.
- This application has received Scientific Review.
- This application is for a PACE unit
HREC and Subcommittee Review

There are four key questions that will display on the ‘Admin only’ page. The instructions for each of these are provided below:

12.1 Is this application ready to be approved/noted?
   * i.e. Have all the attachments been supplied and all the action comments (if any) been resolved?
   
   ![Radio buttons for Yes or No]

12.3 Please adjust this question before using the Action menu.
   Current committee providing review:
   ![Dropdown for committee selection]

12.3.1 Have you marked each and every committee member comment as “Confidential”? *
   
   ![Radio buttons for Yes or No]

12.4.3 Has a rejection letter (i.e. “Not Approved”) been sent from ethics.secretariat@mq.edu.au (Research Office) or the relevant Subcommittee email address? *
   
   ![Radio buttons for Yes or No]

**Confirming attachments and action notes (12.1)**

This question serves as a reminder to confirm that all the attachments required for ethical review to take place have been supplied and that all the feedback raised by the committee members and committee secretaries (via the ‘Action Note’ function) has been addressed and resolved.

Once you are able to confirm that all required attachments have been provided (see Attachments section) and that all action notes – if any – have been resolved (i.e. no red or amber flags), please answer “Yes” at question 12.1.

12.1 Is this application ready to be approved/noted?
   * i.e. Have all the attachments been supplied and all the action comments (if any) been resolved?
   
   ![Radio buttons for Yes or No]

12.1.1 Completeness check last performed by (initials): *
   
   ![Field for initials]

This will trigger question 12.1.1 to appear. Please enter your initials at question 12.1.1 and click the Save icon.
Confirming current committee (12.3)

This question is mainly used to help keep track of the committees that have reviewed an application. It is also used when projects that were initially identified by the system as being greater-than-low risk are subsequently reassigned to a subcommittee.

When you open this page for the first time, this question will default to the ‘Animal Ethics Committee’ option. As this is not applicable to human ethics application, a red validation message appears underneath the question.

To select a valid response, click on the drop-down list to select the committee currently providing review (from the eight (8) committees mentioned in the validation message).

This validation message provides instructions on how to complete the question and prevents you leaving the page until a valid response is entered.

Once selected, the validation message will disappear.

Confirming ‘Confidential’ comments, approval letter and date (12.3.1)

This question serves as a reminder to confirm that all ‘General Notes’ saved in the application have been checked as ‘Confidential’.

This question defaults to the “No” option, which prevents an application from being moved until you are able to confirm that all ‘General Notes’ have been checked as ‘Confidential’. If there are no general notes in the application, select “Yes”.

Once you are able to select “Yes”, question 12.4.1 will appear, asking you to attach the approval letter to the Attachments section.

Similarly, if and when you are able to select “Yes” at 12.4.1, you will be asked to provide your initials at 12.4.2. This will also automatically generate the current date to appear in question 12.4.2a.

You can now select the Approve application link in the Action tab.
Rejection letter and date (12.4.3)

If and when the committee renders an application as “Not Approved” via the Review Outcome function, the committee secretary will be required to send the rejection letter to the applicant(s) regarding this outcome.

This question serves as a reminder to send the email first – from the relevant email address – before finalising this outcome in the system.

Once you have sent this email, you will be able to answer “Yes” at question 12.4.3.

This will trigger question 12.4.3a to appear with the current date automatically entered.

You can now select the Reject application link in the Action tab.
External Review – Research Office only

In order to successfully process an External Review application (i.e. Application status = External Approval Noted), you will need to follow these steps:

1. **At question 12.1**, confirm that all attachments (see *Attachments* section) and all action comments (coloured flags) have been addressed by answering "Yes".

2. **At question 12.1.1**, *supply your initials* as part of confirming the application is complete.

3. **At question 12.2**, confirm that the application is ready to process by answering "Yes".

4. **At question 12.2a**, leave the current date (populates automatically) and follow the instructions for the *External approval noted* action.
Scientific Review – Research Office only

In order to open the Scientific review section of the form, the committee secretary must first select “Scientific Subcommittee” from the drop-down list in question 12.3.

This will subsequently open question 12.3s.

Select “Yes” at question 12.3s and press the Save icon.

Note: If scientific review is not required, leave this answer as “No” and select the ‘Forward to HREC’ action.

The Scientific review section will now appear at the bottom of the Form tab.

You will now be able to assign an initial reviewer to complete these pages. Once the initial reviewer lodges their decision, you will receive an email.

At this point, you will be able to assign additional reviewers or the whole committee in the same fashion.

Once all reviewers have lodged a decision, you will receive an email once more – if there is a delay in responses, you may choose to use the Reminder action.

When the application is ready to be forwarded to the HREC (MDS):

- go to the Forms tab
- select the ‘Recommendations’ page
- enter the current date into question 13.12: “Date Forwarded to HREC”
- in the Action tab select ‘Forward to HREC’
Actions: Reassigning applications

Depending on which state an application is in, the Action menu in the left-hand side pane offers up to three (3) options that will allow you to reassign the form to a different committee.

Forward/Reassign to HREC

In the **Scientific** state, the ‘Forward to HREC’ action will send the application to the HREC (MDS) state and notify the secretary whether or not scientific review has taken place.

In the **HREC (HUM)** and **HREC (MDS)** states, the ‘Reassign to HREC’ action will send the application to the other HREC state (e.g. in HREC (MDS) state the action will send to HREC (HUM) state).

In **Subcommittees** and **MGSM** states, the ‘Reassign to HREC’ action will send the application to the HREC deemed most appropriate by the system (based on responses saved in the form).

*Note:* Prior Review applications cannot be reassigned.

Reassign to Sub委员会

This action is only available in the **HREC (HUM)** and **HREC (MDS)** states.

Before using this action, you will need to select the relevant subcommittee from the drop-down list in **question 12.3: “Current committee providing review”**.

*Note:* Prior Review applications, proposals from an external primary contact and some greater-than-low risk applications cannot be reassigned to an ethics subcommittee.
Reassign to Scientific

<table>
<thead>
<tr>
<th>Form</th>
<th>Review</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reassign to HREC (HUM)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reassign to Subcommittee</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reassign to Scientific</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

This action is only available in HREC (MDS) state.

The ‘Reassign to Scientific’ action will send the application to the Scientific Subcommittee for scientific review.

Once scientific review is complete, the application will be returned to the HREC (MDS) via the ‘Forward to HREC’ action.
4. Assigning and removing reviewers

To assign or move reviewers for an application, you will need to navigate to the left-hand side pane and select the Review tab.

Assigning reviewers

Once in the Review tab, select the first option in the list, i.e. the name of the committee currently providing review.

The committee secretary’s name should automatically appear in the list with the ‘Executive’ box checked.

**Note:** Do not uncheck/deselect the ‘Executive’ box, as this will remove necessary permissions.

1. To assign access for this application to individual reviewers, enter each name/MQ OneID separately into the “Select Reviewer” textbox and click on the magnifying glass. This will either
   a. automatically add the person (if the search criteria is unique), or
   b. show a list of options to select. If this (b) occurs, please select the most relevant record in the list by checking the criteria in the each column. For instance, if there are multiple records for the same person, the most recent record should have an MQ OneID/student number.

2. To assign access for this application to a committee, select the committee name using the “Add Committee” drop-down list.
3. **Check the ‘Executive’ box and enter the ‘Review by’ date** for each person you wish to make a reviewer.

4. Once all the dates are entered, go to the left-hand side pane once more and select ‘Reviewer assignment history’.

5. Select the checkboxes for the relevant reviewers in the list (or select the checkbox in the header to select all)

6. Click the ‘**Notify Selected Reviewers**’ link to send an email to each reviewer with their respective ‘Review by’ date.

7. Once this is complete, the text in the ‘Notified’ column will change from “No” to “Yes”.

**Remove reviewers**

**Note:** You cannot remove a reviewer who has already lodged their decision. Removing a reviewer does not remove their comments – these will need to be deleted separately. Do not uncheck/deselect the ‘Executive’ box, as this will remove necessary permissions.

Select the first option in the **Review** tab list, i.e. the name of the committee currently providing review.

To remove access permissions for anyone appearing in the list, use the checkboxes on the left side of the screen to *Delete Selected* or click on the relevant trashcan icon on the right side.
5. Viewing the review outcomes

Once all reviewers currently assigned to an application have each lodged a decision (i.e. review outcome), the system will once again send an email to the shared administrator address for that committee (e.g. ethics.secretariat@mq.edu.au). When this occurs, please follow the instructions in the Logging in and locating an application section to access the form identified in the email.

Upon opening the application, navigate to the Review tab once more and select ‘Review Outcome’ to see the decisions made by all previous reviewers.

The list of outcomes will appear in the last column (on the right side) of the Review Outcome table.

This list should assist in determining whether further review is required, whether additional information is required (from the applicant(s)) or if an application is ready to be completed (e.g. approved, not approved, etc.)
6. Managing page comments

Reading page comments (‘General Notes’)

All comments from committee members are to be placed on the ‘Committee comments’ page – the presence of at least one General Note will be indicated by a blue flag. If any comments appear on the ‘Committee comments (Spare)’ page, please ensure that these are also read.

To navigate to this page, click on the Form tab (if not already selected) in the left-hand side pane and in the Committee details section click on the ‘Committee comments’ page.

Once on this page, go to the top right-hand pane and click on the Page Comments icon (small speech bubble picture on a page).

This will open the Page Comments box, listing all of the comments in reverse chronological order – beginning with the most recent comment.

To read each comment in full, hover over or click on the hyperlinks in the ‘Comments’ column.

When you are finished reading comments, press ‘OK’ or the ‘x’ to close the Page comments box.
Converting to ‘Confidential’ comments

**Note:** Before an application can be moved to another state, the Admin only section (in the Form tab) asks you to make each committee member comment ‘Confidential’. This is so the system can prevent applicants from viewing confidential comments.

This is best managed by checking the ‘Confidential?’ box upon initially reading each comment.

To save this change, you must also select the green tick in the bottom right-hand corner of the Page Comments box.

Once this is complete, the text in the ‘Confidential?’ column (of the Page Comments table) will change from “No” to “Yes”.

Action: Remind reviewers

To remind reviewers to comment on an application – particularly if the Review (Due) Date is drawing near – the committee secretary may choose to use the ‘Reminder’ link in the Action menu.

This will send a link to all current reviewers where the ‘Executive’ box is checked (see Review tab).
Collating feedback for applicants (‘Action Notes’)

If the committee requires additional information from the applicant(s), this feedback will need to be collated by the committee secretary into one or more ‘Action Notes’.

There are three stages of Action Notes:

1. New action notes as a red flag
2. Action notes that have been addressed by an applicant as an amber flag
3. Action notes that are considered ‘resolved’ (by the secretary) as a green flag

Each ‘Action Note’ will need to be placed on the corresponding page in the form, i.e. where changes are required to specific questions. For instance, changes to the project summaries (questions 1.4 and/or 1.5) would require an action note to be placed on the Summary page (in the section “1. Key aspects”).

As a result, when the application is sent to the applicant(s) for the requisite changes, applicants will be able to edit the pages with action notes, while the remaining pages appear as ‘read only’ (i.e. no further editing).

**Note:** If the changes required are known to trigger additional pages, you will need to request a ‘Redraft’ via the Ethics Administrator (in the Research Office) once all Action Notes have been written – i.e. instead of using ‘Request additional information’.

To attach an action note, navigate to the page(s) requiring changes (as per the committee’s feedback) and select the Page Comments icon.

In the Page Comments box, click the ‘New Comment’ link and select the ‘Action Note’ button.
Enter the comment, with enough detail for the applicants, and select the green tick to save.

The saved comment will now appear in the Page Comments table (see below).

Once you have completing adding action notes to a page, press ‘OK’ to exit. Now a red flag will appear next to both the page and the section in which the action note was placed.

This will assist the applicant(s) in locating and responding to each of the action notes.

When you have completed the process for ‘Confidential’ comments and ‘Action Notes’, you will need to:

- answer “Yes” at question 12.3.1 (i.e. are all committee comments ‘Confidential’?)
- answer “No” at question 12.4.1 (i.e. is the project ready to be approved?), and
- select the Request additional information link from the Action tab.
7. Actions: Progressing applications

Depending on which state an application is in, the Action menu in the left-hand side pane offers up to four (4) options regarding processing the application.

External approval noted – Research Office only

Select the ‘External approval noted’ link from the Action tab to process a successful External Review application to the “Complete” state.

This will send an email to the applicant(s), notifying them of the outcome.

Request additional information

Select the ‘Request additional information’ link from the Action tab once all committee comments have been made ‘Confidential’ and all ‘Action Notes’ have been added to the relevant pages.

Once the workflow state has been changed – before exiting the application – you will need to ensure there is a green tick present next to the ‘Admin only’ page (and not ?). To do so, navigate to the page and click the Save icon. In the meantime, an email will be sent to the applicant(s), notifying them of the outcome.

Approve

Select the ‘Approve application’ link from the Action tab once an approval letter has been attached to the ‘Documentation’ page and the approval date has been entered on the ‘Admin only’ page.

This will change the workflow state and send an email to the applicant(s), notifying them to login to IRIS in order to access their approval letter.

Reject

Select the ‘Reject application’ link from the Action tab once a rejection letter has been sent by the committee secretary and the rejection date has been entered on the ‘Admin only’ page.

This will change the workflow state and no automated email will be sent.
Meeting functions – Research Office only

To help differentiate between applications that undergo online ethical review only and applications that are reviewed at a HREC meeting, the HREC secretaries are able to create a list of HREC meetings and assign applications to these meetings.

Create meetings

To create a meeting, navigate to Ethics >> Manage Committee Meetings.

This will open up the current list of meetings in the system.

If your meeting is not in the list, select the ‘Create New Meeting’ link on the left side of the screen.

Enter the relevant information in each field provided and select the Save button.

This meeting will now be saved in your list. If you wish to view the full list of meeting for a specific committee, navigate to Ethics >> Committees and Registers. Select ‘Human’, followed by the relevant HREC, and a full listing will appear on the left-hand side of the screen.
Assign to a meeting

Once the relevant meeting is shown in the list, navigate the Ethics >> Manage Applications to find the application you wish to assign to a HREC meeting.

Once you have selected ‘Filter your Applications’ and conducted an advanced search (click here for instructions), you should be able to locate the relevant application(s) in the results list.

To begin assigning applications to a meeting, select the relevant checkboxes in the results list (to highlight the row(s)) and click on the ‘Assign to Committee Meeting’ link.

A page titled ‘Assign application(s) to a meeting’ will appear.

Select the relevant meeting from the drop-down list underneath the page title. This will load the details of the meeting.

To confirm that you wish to assign each application to the meeting selected, simply click the Save button at the bottom of the screen. This meeting will now appear as a hyperlink in the table.
Action: Meeting – optional

Once you have assigned an application to a meeting, you may also wish to use the ‘Meeting state’ link in the Action tab. This will change the state to ‘Meeting’ move the application into a ‘Read only’ mode.

If there is no conflict of interest with this committee (as per question 12.0a), it will automatically add all current committee members listed in the database as being able to view the application.

If there is a conflict of interest with this committee (as per question 12.0a), only the secretary will be automatically added to view the application – all other access will need to be assigned manually via the Review tab. In such instances, only the committee secretary should have the ‘Executive’ box checked – all committee members should have the ‘Executive’ box unchecked (i.e. empty).

Once in the ‘Meeting’ state, the committee secretary can read all application pages, enter and save minutes or notes on the ‘Secretary comments’ page and add ‘Action Notes’.

Meanwhile, committee members will only be able to read an application – preventing any further comments from being added.

Access to ‘Meeting’ state

Secretary

The committee secretary will be able to access applications in the ‘Meeting’ state via Ethics >> Applications >> For Review.
Committee members

Committee members will need to filter applications via Ethics >> Manage Applications.
The best method is to search based on “Meeting Date”.

Note: Once the results list is generated – to prevent running the search again – members will need to use the ‘back’ arrow at the top of their browser to return to this list (the example provided is using Google Chrome).

Action: Return to HREC (from Meeting state)

At the conclusion of the taking minutes/adding action notes, each application assigned to the ‘Meeting’ state will need to be returned to the respective HREC state.

This will be determined based on the answer at question 12.3.

Use the ‘Return to HREC’ link in the Action tab to complete this process.
Exiting and logging out

Go to the top right-hand pane and click on the Exit icon (folder with green arrow pointing upwards).

A warning message will appear asking if you wish to save changes. To save changes to the form when exiting, click the “OK” button. This will take you back to the “Applications” screen.

When you are ready to logout of the system (i.e. IRIS), select the grey “Logout” button at the top-right of the screen. This will return you to the IRIS login page.
Resubmissions

Resolving ‘Action Notes’

Once an application is returned to a committee (either from ‘Additional Information Requested’ or ‘Redraft’ status), all ‘Action Notes’ that previously appeared as a red flag will now be amber, indicating that a response to the committee’s feedback has been applied.

Navigate to the relevant page(s) to confirm that the appropriate changes have been made. If further review is required, be sure to assign reviewers.

Once you are able to confirm that the appropriate changes have been made, go into the Page Comments area for each page with an amber flag.

**Note:** If the appropriate changes have not been made, add a new ‘action note’ on the same page before ‘Requesting additional information’ once more. When the changes are finally resolved, mark both amber flags as being resolved.

To mark comments as being “Resolved”, select the relevant checkbox(es) to highlight each comment and click on the ‘Mark Selected Comments as Resolved’ link.

A confirmation message will appear – press OK to proceed. Now “Yes” will appear in the ‘Resolved’ column for each selected comment.

When you press OK to exit the Page Comments box, the corresponding amber flags will now be green.

Once all action notes have been resolved (i.e. no amber flags), you will be able to confirm this on the ‘Admin only’ page and approve/note the application.
Withdrawing approval ("discontinue")

If you need to withdraw the approval of an application (e.g. if the project is found to be in breach of the conditions of approval), please follow the instructions below.

**Instructions**

1. Log into IRIS and locate the approved application on the **Ethics >> Applications** screen.

2. Select **Discontinue application** from the **Action** tab.

3. A prompt box will appear, reminding you to complete the "Changes to project" page after you press **OK**.

   You will remain logged in to the application; meanwhile the application status will change to "Withdrawal Requested" and the workflow state to "Withdrawing".

4. The form will now begin on a new page titled "Changes to project". Select "Yes, I wish to discontinue".

5. Once the following question (ii.) is populated with the current date, you will need to provide a response to the final question (iii.) and select the **Save** icon.

6. Return to the Action menu and select **Process withdrawal**.

---

*Note:* The diagrams provided are placeholders for the actual user interface elements described in the instructions.
## Appendix A: Status table

<table>
<thead>
<tr>
<th>STATUS NAME</th>
<th>USAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Draft</td>
<td>Default status for new applications</td>
</tr>
<tr>
<td>Pending</td>
<td>Waiting for signoff (internal applicants only)</td>
</tr>
<tr>
<td>Secretariat Review</td>
<td>Processing External Review applications</td>
</tr>
<tr>
<td>Scientific Review</td>
<td>Scientific review of ethics applications</td>
</tr>
<tr>
<td>HREC Review</td>
<td>Ethical review of Greater-than-Low Risk applications</td>
</tr>
<tr>
<td>Subcommittee Review</td>
<td>Ethical review of Low Risk applications</td>
</tr>
<tr>
<td>Additional Information Requested</td>
<td>Changes are required before resubmission</td>
</tr>
<tr>
<td>Redraft</td>
<td>Significant changes are required before resubmission</td>
</tr>
<tr>
<td>Resubmission</td>
<td>Ethical review of applications that have been resubmitted following a request for additional information</td>
</tr>
<tr>
<td>Approved</td>
<td>Successful completion of Full Review, Prior Review or Scientific Review form</td>
</tr>
<tr>
<td>External Approval Noted</td>
<td>Successful completion of the External Review form</td>
</tr>
<tr>
<td>Not Approved</td>
<td>Unsuccessful attempt to complete an ethics application</td>
</tr>
<tr>
<td>Withdrawal Requested</td>
<td>Requesting to withdraw or discontinue an application</td>
</tr>
<tr>
<td>Withdrawn</td>
<td>Application withdrawn from the ethical review process</td>
</tr>
<tr>
<td>Discontinued</td>
<td>Previously-approved projects that will not be completed and/or have had ethics approval withdrawn by MQ</td>
</tr>
<tr>
<td>Reapproved</td>
<td>Reinstating ethics approval after discontinued by MQ</td>
</tr>
<tr>
<td>Archived</td>
<td>For completed projects that have sent through a final report or for applications that are left inactive for 42 days</td>
</tr>
</tbody>
</table>