This guide is provided for Researchers and students applying for Human Ethics Clearance

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 complete and submit the Human Ethics Application Form to obtain approval from one of Macquarie University’s Human Research Ethics Committees (HRECs) or Ethics Subcommittees.

This user guide will help you to accurately input your data into the form.

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 should use this form?

All staff and students of Macquarie University (MQ) and Macquarie University Hospital (MUH) who will be conducting research involving humans should apply to MQ’s Human Research Ethics Committees (HRECs) for ethical review. The form is also open to businesses, organisations and members of the public who are not affiliated with MQ (i.e. external applicants).¹

MQ’s HRECs cannot provide ethical review for sites affiliated with Public Health, Justice Health or the Australian Department of Defence. These government departments have their own HRECs, whose details can be found at the National Health and Medical Research Council (NHMRC) website.

Once submitted, you will be able to track the progress of your application online.

What forms does it replace?

If you are submitting a new ethics application, then you 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 Please note that this form is being introduced progressively across the university, one faculty at a time. For further information on this schedule please visit the MQ Online Forms and MQ Human Ethics websites.
Logging in and creating an application

Go to the IRIS website (https://iris.mq.edu.au/RMENet/) and enter your MQ OneID or Student User Name and Password.

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

Select Create Application as shown below.

Select the hyperlink titled called Human Ethics Application Form (note: the version number may change in accordance with regular reviews and updates). This will create and open a new Human Ethics Application Form for you to complete.
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?"

Each new application initially appears with the title, "[Main Title]: Sub-title". Once the new title is saved, this will appear in the top-left pane.

2. Application status
This displays information that describes the progress of the application to date.

The default status for each new application is Draft – indicating that the application is under development and has not yet been submitted.

Once the application has been successfully submitted, this status will continue to change throughout the application process. Some other examples include:

- Pending (internal only – with signoff party)
- HREC Review (under review by HREC)
- Subcommittee 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.

The default state for each new application is Draft – indicating that the application is being edited by the applicants. Some other examples include:

- HREC (HUM)
- HREC (MDS)
- Subcommittees
- Request for Information
2. Left-hand side pane

There are two (2) 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.

   A red exclamation mark (❗) indicates that there are mandatory fields that have not been completed on the page (including questions within the “table” questions).

   Note: The form will determine which sections are required to be completed based on answers to specific questions. Thus some sections will only appear as an application progresses.

   Should the form present you with a question mark (❓) next to any of the pages (while completing or submitting), this is the system suggesting that the answers on these pages may need to be revised before continuing. In some instances, there may be additional questions that require an answer.

2. Action
   This contains action links. These will carry out requests that are available to the user at this point in the workflow. Examples include:
   - Delete application (before submission)
   - Withdraw application (after submission)
   - Email PDF (to other known investigators)
   - Notify research personnel
   - Submit application
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 your 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.
Personnel details (section 2)

The Human Ethics Application Form will automatically include your personnel details as they are currently stored in Human Resources. If any of these details are incorrect:

- MQ staff can change their personal information via HR Online
- MQ students can change their personal information via eStudent
- All other applicants should contact MQ Informatics via OneHelp or +61 2 9850 4357.

If the creator of the form is not listed in the Personnel table when the application is submitted, they will not be included in any of the ethical review correspondence.

When a person appears in the Personnel table for the first time, the position title question defaults to “Not Specified”. This position will need to be updated in accordance with each person’s role for the project – unless the form instructs you otherwise.

Position titles

The application form lists the following positions:

- **Student**: To be used where any investigator is participating in a student capacity (i.e. as part of a degree or course).

- **Principal Investigator** (or PI): To be used in the following circumstances:
  - (if the project is for student research) to identify the Principal Supervisor of the student(s)
  - to identify the lead researcher and, therefore, the primary contact
  - (if MQ is providing ethical review for more than one institution/site) to identify the lead researcher at each institution/site

- **Coordinating Investigator**: To only be used if MQ is providing ethical review for more than one institution/site (i.e. Multi-site Review). This role, when required, must be nominated as the primary contact because the Coordinating Investigator is responsible for coordinating reports from the various Principal Investigators and reporting back to MQ.

- **Overseas Investigator**: To be used to identify any investigators based outside Australia.

- **Associate Investigator**: Typically an investigator who provides intellectual input into the research and whose participation warrants inclusion of their name on publications.

- **Investigator**: For other investigators who do not fit into the preceding categories.

- **Research Coordinator**: For roles whose purpose is to organise/coordinate the project/personnel.

- **Research Assistant**: Assists with research and administrative tasks; may be included on publications.

- **Other personnel**: Not an investigator; for other personnel who do not fit into any of the preceding categories.
Instructions

**Question 2.1:**
Click on your name to see if all your details are current and answer additional questions relating to your ethics application.

The table row containing your name will be expanded underneath. Some of the information will automatically appear as it is pulled from our records. These entries are greyed-out and cannot be edited.

Once you have confirmed that everything is correct and completed any mandatory questions, select the green tick icon in the bottom-right corner of this dialog box. To cancel, select the red cross icon.
Search and add other investigators

**Question 2.1 (continued):**
Add other research personnel on your project, by first searching their details on the database.

The most straightforward method for searching is to enter your MQ OneID or student number, then select the magnifying glass icon to execute the search.

The search function can also search on first and/or last name. However, results and loading time will vary based on the prevalence of those names in our records.

If you would like to search by any other criteria, you can use the More Criteria hyperlink.

Selecting this will open up an advanced search with additional options to narrow your list of results. Select Clear to clear all fields, or Cancel to close the advanced search.

Selecting the person you want from the list will automatically add them (and their respective details) to your investigator list.

**Note:** When multiple entries for the same search criteria appear, please select carefully to ensure you have the right person from our records. If there is more than one record for the one person, please prioritise the ID that begins with “MQ”.

In the Search & Add Person popup window is a link titled Add External Person. This lets you manually add someone who cannot be found in your search. Selecting this link will open another dialog box where you can add all their details, project position and qualifications.
Question 2.1 (continued):
Adding an External Person (if needed)

Once you have confirmed that everything is correct and completed all mandatory questions, select the green tick icon in the bottom-right corner of this dialog box. To cancel, select the red cross icon.

These updates will be reflected in the Personnel table.

If you change your mind and wish to remove any personnel in your list, simply select the Bin icon.
Research locations (section 3)

Question 3.1:
This form introduces a new multi-purpose question about where the research is being conducted:

3.1 Regarding the ethical oversight to be provided by MQ, at which locations will the research be conducted? Please select all that apply.

This question helps to differentiate between the following situations:

- **External Review** applications (Not applicable - external review only)
- Projects being conducted **onsite**, by selecting:
  - Macquarie University (including MQ Clinics, MGSM, City Campus, etc.)
  - Macquarie University Hospital
- Projects where the research is not being conducted at MQ/MUH (i.e. **offsite**), by selecting:
  - Other universities in Australia (one or more)
  - Other private hospitals in Australia (one or more)
  - Private health practices/clinics in Australia (one or more))
- Projects requiring ethics approval from a specific **external HREC**, by selecting:
  - Public hospitals in Australia (one or more)
  - Other public health/justice health sites in Australia (one or more)
  - Australian Department of Defence sites (one or more))
- Projects being conducted at **other locations in Australia** (Other locations in Australia)
- Projects involving **site-specific approaches** (e.g. SERAP), by selecting:
  - In participants’ homes
  - At participants’ place of work
  - Public schools
  - Private/independent schools
- Projects being conducted **overseas** (Overseas i.e. not in Australia)

Additional help text is provided for this question in the application form.
**Question 3.1.2:**

Certain responses to 3.1 will also trigger the following question:

3.1.2 Will you be asking a Macquarie University HREC to provide ethical review for research to be undertaken at institutions, organisations or businesses that are external to MQ/MUH?

If you respond “Yes”, then additional questions will appear regarding:

- the number of external sites to be reviewed by MQ
- the name and location of these sites
- any conflicts of interest, and
- any differences in the way the project is conducted at the separate sites.
Involvement of other HRECs (section 3)

Question 3.2:
The following question helps to further differentiate between the three (3) types of application pathways built into this single online application form:

3.2 Has this research proposal been submitted to any external HRECs?

Application pathways

Full Review (formerly MQ Ethics Application Form and its Appendices)
Standard ethics application form, including information relevant for the ethical review of multi-centre research.

Prior Review
For projects with current ethics approval from an external HREC, which seek to obtain ethical review from MQ for one or more additional sites (e.g. MQ, MUH, other private hospitals, etc.). All Prior Review applications need to answer “Yes” at question 3.2.2.5. If this question does not appear for you, check with the Ethics Secretariat to determine your eligibility.

External Review (formerly External Application Approval Form)
For internal applicants conducting externally-approved projects at one or more offsite locations (i.e. does not take place at MQ or MUH). All External Review applications need to answer “Not applicable - external review only” at question 3.1.

Should you wish to apply for External Review or Prior Review at MQ, you will need to:
- cite and attach a copy of the external application
- cite the external HREC involved and the current status of your application (i.e. Approved)
- attach a copy of your final approval letter and
- attach a copy of all your approval correspondence (with the external HREC)

Please remember that all Prior Review applications need only report on project details that:
- apply to the sites for which MQ will be providing ethical review, and
- have not already been detailed in your external ethics application (e.g. NEAF)
Type of research (section 5)

This form has revised the list for types of research being undertaken:

5.1 The nature of this project is most appropriately described as involving: (please select all that apply)

The options in this list are one of the factors that help to determine whether the project qualifies as being greater-than-low risk. Some of the options in this list also trigger additional questions throughout the form and assist in identifying the need for specific attachments.

The newest addition to this list is the option “Use of medical imaging/equipment”, which (when selected) will trigger question 5.1.3 (see below).

Note: Proposals involving ionising radiation should refer to the ARPANSA Radiation Protection Series.

Proposals involving gametes or embryos should refer to the Ethical guidelines on the use of Assisted Reproductive Technology in clinical practice and research (2007).

If you are unclear on which – if any – category (or categories) applies to your research proposal, please refer to section three (3) of the National Statement on Ethical Conduct in Human Research (Ethical considerations specific to research methods or fields).
Research participants (section 6)

This form has also the list for types of research participants:

6.1 Please indicate which of the following 'types of research participants' are likely to be included in your research proposal due to the project design.

- Women who are pregnant and/or the human foetus
- Children and/or young people (i.e. under 18 years)
- Wards of state
- MQ students, MQ staff, MUH staff and/or MUH patients
- People in teacher-student relationships
- People in employer-employee relationships
- People with chronic conditions/disabilities and their carers
- Healthcare professionals and their patients/clients
- People in other professional-client relationships
- Prisoners or detainees
- Refugees or asylum seekers
- Members of the Police Force
- Members of the Defence Force
- People highly-dependent on medical care
- People with a cognitive impairment, an intellectual disability or a mental illness
- People who may be involved in illegal activity
- Aboriginal or Torres Strait Islanders
- People residing outside Australia
- People whose primary language is not English
- None of the above

Similar to 5.1, the options in this list are one of the factors that help to determine whether the project qualifies as being greater-than-low risk. Some of the options in this list also trigger additional questions throughout the form.

Note: "MQ students" and "MQ staff" include (among others) MGSM, ASAM and MQ City Campus.

"Children and/or young people" refers to persons under eighteen (18) years of age.

If you are unclear on which – if any – category (or categories) applies to your research proposal, please refer to section four (4) of the National Statement on Ethical Conduct in Human Research (Ethical considerations specific to participants).

If none of these categories apply, please select "None of the above".
Attachments (section 10)

Supporting documentation can be attached as a **soft copy** by using the Attachments table.

### Instructions

#### Adding documents

The **Add New Document** hyperlink allows you to attach necessary documents such as recruitment and consent information.

Please note that there is a 40MB limit for each attachment. Once you have selected **Add New Document**, a new row will appear, asking you to enter a **Document Description**. Once this field is completed, **click the green tick** to confirm.

You may then click the upload icon (under “**Soft Copy**”) to open the “Upload File” window. **Choose file** to search on your device, enter “Description” (optional) and select **OK**.

A checkbox will be ticked in the “Soft Copy” column once the attachment has been uploaded successfully. Each attachment can be accessed via its hyperlink or the Reports icon.
Signoff (section 11)

Metadata

The *Australian Code for the Responsible Conduct of Research* states:

"Research data should be made available for use by other researchers unless this is prevented by ethical, privacy or confidentiality matters." (Item 2.5.2: Retain research data and primary materials).

Applicants may indicate their intention to share the data/biospecimens collected as part of their research project at question 6.4.6 (‘Consent specifics’ page).

This will subsequently trigger the 'Metadata' page to open in the ‘Signoff’ section. This page asks if the research personnel consent to being contacted by Macquarie University’s ResearchOnline staff upon the submission of the project’s final Human Ethics Annual Report. The reason for this is to determine if you would like to include a description of your new dataset in the Research Data Australia (RDA) database.

Note: Responding with a "Yes" at this question does not mean you are (at this point) agreeing to share actual research data collected during your research – it means you are simply agreeing to be contacted upon submission of your final Human Ethics Annual Report ("final report") to determine if you will make your metadata discoverable via Research Data Australia (RDA).
External Review

If your application fits the criteria for the External Review form, you will be asked to confirm that all research will be undertaken offsite at question 11.1x. You will not be able to submit your application until this question has been completed.

<table>
<thead>
<tr>
<th>11.1x In order for this External Review application to be submitted, you must first confirm that this research will not be taking place on MUH or MQ premises (this also includes MGSM, ASAM and MQ City Campus).</th>
</tr>
</thead>
<tbody>
<tr>
<td>I can confirm that this research will not be taking place on Macquarie University or Macquarie University Hospital premises.</td>
</tr>
<tr>
<td>I agree</td>
</tr>
</tbody>
</table>

Conflict of Interest

Before submitting any application, the research personnel are first required to fully-disclose any possible conflict of interest with the MQ application process at question 11.1x:

**Note:** Declaring a conflict of interest here will not prevent you from submitting your application.

11.1 This question relates to all research personnel listed on this application.

Please declare any conflict of interest that is likely to occur as a result of the signoff and ethical review process by indicating which of the following statements apply to you: *(please select all that apply)*

<table>
<thead>
<tr>
<th>This question relates to all research personnel listed on this application.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Please declare any conflict of interest that is likely to occur as a result of the signoff and ethical review process by indicating which of the following statements apply to you: <em>(please select all that apply)</em></td>
</tr>
<tr>
<td>I am a Head of Department or other signoff party</td>
</tr>
<tr>
<td>I amhave been supervised by my Head of Department or other signoff party</td>
</tr>
<tr>
<td>I am related to in a spousal relationship with the relevant signoff party</td>
</tr>
<tr>
<td>I am a member of a MQ HREC or Faculty Ethics Subcommittee</td>
</tr>
<tr>
<td>I am related to in a spousal relationship with a member of the relevant HREC/Subcommittee</td>
</tr>
<tr>
<td>I am anokv be an supervisor for a member of the relevant HREC/Subcommittee</td>
</tr>
<tr>
<td>I amhave been supervised by a member of the relevant HREC/Subcommittee</td>
</tr>
<tr>
<td>Other (not listed above)</td>
</tr>
<tr>
<td>I foresee no potential conflict of interest in submitting this research proposal to MQ</td>
</tr>
</tbody>
</table>

This question assists the system – and the administrative staff – in allocating the most appropriate signoff party (e.g. if the Head of Department is involved in the project) and reviewers (if an applicant is also a member of a committee).

If there is no potential conflict of interest, please be sure to only select the last option: “I foresee no potential conflict of interest in submitting this research proposal to MQ”.
Notifications

In some cases, the online form will alert you to any additional institutional and/or administrative requirements if your research includes any of the following:

- Research funded by a sponsor
- Proposals from external applicants
- Research involving pregnant women as participants
- Research involving children under five as participants
- Phase I clinical trials

**Note:** If you know this is the case before you commence a new human ethics application with MQ, please consider planning ahead by undertaking the relevant actions listed in the screenshot above.
Signoff table

Each Principal Investigator, Student and Coordinating Investigator will be required to sign off before submitting the application.

Each of these investigator types will be automatically listed in the Signoff table. Before an application can be submitted, each individual will need to log in to the application, open their own record in the Signoff table and accept the terms of submitting the application (i.e. “signoff”).

Those listed in the “Type” column as “External” – who may not have access to IRIS – may ask for the Principal Investigator to sign-off on their behalf.

Instructions

Signing-off

Upon clicking on your name at the signoff page, you will be presented with the expanded view below. Accept and provide the signoff date. Click on the green tick to confirm.

**Note:** Signoff is required from each investigator listed in this table in order for the application to be submitted though the online system. Each individual investigator listed must log in separately and complete their signoff.

To remind or advise other members listed in the Signoff table to accept the terms of submitting this application to MQ, you may use the Notify research personnel link in the Action menu.
Actions: Draft applications

The Action menu in the left-hand side pane contains a list of actions that you can undertake during the drafting process.

Email application and attachments

Instructions

Action Tab: Email PDF

The Email PDF link will allow you to email your application and/or any attachments to yourself or other parties.

When you select this menu option, a message (asking you to press OK) will appear.

Once you’ve pressed the OK button, a box called “Recipients and Document List” will appear on the screen, allowing you to:

1. Search for people to receive documents
2. Select people to receive documents
3. Select documents to send
4. Select a sending option
Delete application

Instructions

Action Tab: Delete (Draft only)

The **Delete (Draft only)** link will delete your application and remove it from the system permanently. You cannot retrieve your application once it has been deleted from the system.

If you have already submitted the application for review and have been asked to “redraft” your responses (i.e. **Application Status = Redraft**), you are no longer able to delete your application – you can only use the **Withdraw (Redraft only)** option.

Advise others regarding signoff

Instructions

Action Tab: Notify research personnel

To remind or advise other members listed in the Signoff table to accept the terms of submitting this application to MQ, you may use the **Notify research personnel** link.

If the Signoff table is incomplete, this action will send an email to each person listed (with a valid email address) notifying them that at least one (1) member is yet to complete their signoff details.

If the Signoff table is complete, this action will send an email to each person listed (with a valid email address) notifying them that the application is ready to be submitted.

Submit application

Instructions

Action Tab: Submit application

Once you have completed your human ethics application, you may use the **Submit application** link.

*Note: This link will not appear for students, as applications can only be submitted by supervisors.*

Please see the next section for more details on **Submitting your application**.
Submitting your application

Avoiding accidental submission

When the Submit application link is selected, a warning message will first appear. If you have selected this in error or you need to return to your application, click the “Cancel” button.

Note: If accidentally submit your form, or need to correct a mistake in a submitted application, you can do so by lodging a OneHelp ticket and directing it to the Research Office as soon as possible.

Ready to submit

Instructions

Submitting

Before you attempt to submit your application, it is recommended that you check all mandatory questions have been completed. Click Expand to check if any pages of your application are still incomplete.

When the Submit application link is selected, a warning message will first appear. To confirm that you intend to submit, click the “OK” button. Please be patient as the system processes your application and do not alter your browser until after this action has been completed.

Once submission is successfully completed, you will be redirected to the Applications screen once more.

Note: If you receive an error message, please follow the instructions in the message provided. You may also obtain further advice from the Macquarie University Human Ethics FAQs webpage.
Exiting and logging out

Instructions

Exiting the application/system

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.
Accessing existing applications

Returning to a saved (draft) application

You can continue to make updates until you submit your application. IRIS automatically saves updates when you navigate between sections, but also remember to regularly save your application by using the “Save” icon.

Upon logging in, you can find your saved draft application under Ethics >> Applications, then on the left-hand pane: My Applications >> Draft

You can click on the Application Title to open and continue to work on your saved draft.

Note: An application draft will be saved in the server for approximately 6 weeks. After that period the application will be considered inactive and will be deleted from the system. When this occurs your application cannot be retrieved and a new application will need to be submitted.

Tracking your application’s progress

Once you have submitted one or more applications, you can keep track of the progress within IRIS (Ethics >> Applications) by looking at the status of each application in the system.

Note: Applicants will only be able to access their applications at certain stages in the process – typically after receiving an automated email.

Certain members of the research personnel will each receive emails to their respective address (as identified in the Personnel table), regarding updates to the applications progress, including:

- When the signoff party (e.g. Head of Department) requests changes
- When a committee requests additional information
- When your application is approved (or “noted”, if External Review)
- When your submission is not approved

For more information on the different statuses, please refer to the appendices of this user guide.
Returned applications

Once an application has been received and reviewed, you may be contacted and asked to provide additional information. When this happens, those members of your research personnel who previously completed the Signoff table will:

a. receive an automated email notification asking them to log in to the online application, and
b. be given the opportunity to respond to the requested changes.

Instructions

Once you have received an email for **Additional Information Requested** (or **Redraft**, if the requested changes are significant), return to **Ethics >> Applications** to view your list of applications under the relevant status.

Click on the **Application Title** to re-open your application, view comments and/or respond to comments.

Viewing the approval letter

When an application is approved, the Principal Investigator(s) (and, if relevant, any Students and the Coordinating Investigator) will automatically receive an email – this email is not your approval letter.

To access a copy of your official approval letter, you will need to log back into IRIS and locate your approved application on the **Ethics >> Applications** screen.

The opening screen will state “**Your approval letter has been attached**”. Navigate to the Attachments section and open the approval letter from the Attachments table (via the hyperlink).

Once downloaded/opened, you will be able to save a copy for your own records.
Responding to comments and resubmitting

View comments

Instructions

On the left-hand pane you will see some coloured flags. These indicate the pages where one or more comments have been made.

A blue flag indicates where general notes have been made. General notes can be of any nature and will not stop you from re-submitting the application.

A red flag indicates where action notes have been made. Action notes indicate the pages with content/responses where changes are being requested. Applicants must respond to each action note or you will not be able to re-submit your application.

Select the page(s) where a flag is displayed. Now select the Page comments icon from the top right-hand pane to view the comments that have been made.

A box titled “Page Comments” will appear, listing the comments applied to your application. Click on the Comment hyperlink to view the comment in full.

Once each comment has been read, you will need to respond to/apply the changes requested by the reviewer or relevant administrator. Press OK to close the Page comments box.
Respond and resubmit

An action comment is indicated by a red flag. Once you have applied the changes requested in an action comment, you will need to re-enter the Page comments area (using the Page comments icon) for that page and perform the following:

**Note:** Where additional information has been requested, changes can only be made to the flagged pages – the rest of your application cannot be edited (i.e. “Read Only”). Should you need to change other sections of your application, please contact the Human Ethics team to request a “Redraft”.

**Instructions**

1. Select the checkbox next to the **Action Note** to which you are responding.

2. Click the link titled “**Mark Selected Comments as Responded**” and select the green tick. “Yes” will now appear in the “Responded?” column.
3. If you wish to add a “Response” comment (optional):
   - select **New Comment**
   - type your response
   - select the **green** tick to save the response

4. If you do not wish to add a response comment and/or you have finished responding to all action notes for a given page, press **OK** to exit. You will now see the **red** flag change to **amber**.

5. Once this process is complete for all pages (i.e. all **red** flags are now **amber**), you will be able to resubmit your application. To do so, navigate to the **Action** tab in the left-hand panel and select **Resubmit application** (or **Submit**, if “Redraft”).

**Note**: If resubmission has not been successful and you encounter an error message, please follow the instructions in the message provided (or refer to Submit application for more information). You may also obtain further advice from the Macquarie University Human Ethics FAQs webpage.
Withdraw or discontinue an application

Withdraw

The Principal Investigator(s) (and, if relevant, the Coordinating Investigator) can withdraw an application if it becomes known that the project will not be undertaken.

Instructions

 Withdraw

While logged in to your returned application, select the **Withdraw application** link from the Action menu (or “Withdraw (Redraft only)”, if under Redraft status).

A prompt box will appear, reminding you to complete the “Changes to project” page after you press OK.

You will remain logged in to your application, meanwhile the application status will change to “Withdrawal Requested” and the workflow state to “Withdrawing”.

The form will now begin on a new page titled “Changes to project”. Select “Yes, I wish to withdraw”.

Once the following question (ii.) is populated with the current date, select the Save icon.

Return to the Action menu and select “Process withdrawal”.

Discontinue

If you need to advise the HREC that you will not be completing a current approved project, the Principal Investigator(s) (and, if relevant, the Coordinating Investigator) will be given the opportunity to discontinue the project.

**Note:** MQ may also choose to withdraw (“Discontinue”) their approval of an application if the project is found to be in breach of the conditions of approval.

**Instructions**

1. Log back into IRIS and locate your approved application on the Ethics >> Applications screen.
2. Select Discontinue application from the Action menu.
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 your 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 select the Save icon.
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>