Reviewer Manual
for
Management of Ethics Applications in
Ethics Module
(RMEWIN & Orion)

Version 1 – 6th June 2011
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1. Using this Manual

This manual has been written for ACU’s Human Research Committee who will be required to review Ethics Applications for New Research Projects.

For new Human Research Ethics applications (New, taught units, de-identified data and registration of external ethics approvals), much of the process will be automated through Orion. Once the applicant has submitted their new application, the Ethics Office may request further comments/amendments from the applicant, refer the project proposal to a member of the Ethics Review Panel or refer the project to the Human Research Ethics Committee. All parties will be kept informed at all stages of this process via email, or by monitoring the progress within Orion itself. All notifications and reminders are automated through Orion.

New ACU Project for Human Ethics (ORION)
Projects using only previously collected non-identifiable data (ORION)

Application for Taught Unit Ethics Approval (ORION)
1.1 Queries

If you have any queries while using this manual, please contact Research Services on Extension 3158 or by email to res.performance@acu.edu.au
2. Ethics Application Forms and Uses

- **Ethics Scope Checker**
  - The Ethics Scope Checker has been designed to assist a potential applicant to check whether or not an activity requires University Ethical Clearance. This tool will pose a sequence of questions to guide the applicant through determining whether or not an Ethics application is should be submitted. At the end of this process, the applicant will either be advised that ethical clearance is required and be directed to which form to complete for the application or informed that ethical clearance is not required.

- **New ACU Project for Ethics Approval**
  - The New form is used for new Human Research Ethics applications or occasionally when a modification has been submitted, but contains significant changes requiring a new submission.

- **Modification of Current ACU Project – not in Orion as yet**
  - The modification of Current ACU Project should be used if an applicant wishes to make changes to their project. For example, changes to:
    - Recruitment Process
    - Methodology
    - Personnel
    - Changes to Participant Information Statement/Consent Form
    - Changes to Advertisements

- **Registration of External Ethics Approval**
  - Registration of External Ethics Approval should be used where a researcher needs to register an ethics clearance obtained from an HREC at another institution and where the approving institution will remain the responsible HREC.
  - Transfer of Ethics Approval from another university to ACU is also covered by this form.

- **Project using only previous collected non-identifiable data**
  - Research projects using previously collected non-identifiable data are required to complete an abridged version of the full application form. De-identified data is data that cannot be identified with a named individual.

- **Application for taught unit clearance**
  - An Application for taught unit clearance should be completed when students are required to carry out research as part of taught units in which they are enrolled.
  - In the case of any particular taught unit in which a standard questionnaire is to be completed non-identifiably by the whole student cohort, an application for ethics approval is not required, provided that the data obtained in this manner are simply aggregated and then used by these same student in exercises designed to develop their report writing skills.
  - If students in a taught unit are required to interview one another and/or to interview or administer a questionnaire/survey instrument to people who are not enrolled in that particular unit, ethics approval or exemption from ethics approval must be sought.

- **Annual Progress Report – not in Orion as yet**
  - The Annual Progress Report is used to provide the HREC with a yearly update for research project that required Ethics Approval. It is used by the University to monitor
compliance with the conditions, both standard and special, under which research protocols have been approved. This form also serves as the final report required for reporting to NHMRC.
3. Access and General Maintenance

3.1 Logging In

3.2 Password Management

3.2.1 Changing your Password

Orion passwords are associated with your network login, so will be one and the same. Once you change your network password, the Orion system will automatically pick up the change.

3.2.2 Forgotten Passwords

Forgotten Passwords may be reset using the ‘Reset Wizard’ when logging into the network.

Otherwise please contact the service desk if you are having trouble with password resets.

Email: Servicedesk@acu.edu.au

Phone: (07) 3623 7272

Hours: Mon-Thurs: 7.30am to 7.30pm AEDST

Friday: 7.30am to 6.30pm AEDST
4. Navigation within Orion

The Applications Home Page allows selected users to:

- Create an ethics application using an eForm
- Edit and amend the application
- Submit a completed application for review
- Review an application
- View all ethics applications they are associated with

4.1 Home Page Navigation

The applications home page consists of two areas:

- The function menu on the right which can be accessed to perform functions related to the user’s role
- A list of ethics applications you have permission to see

Standard Columns in the Ethics Applications List

<table>
<thead>
<tr>
<th>Column</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type</td>
<td>Type of Ethics Application</td>
</tr>
<tr>
<td>Application ID</td>
<td>The ID number automatically assigned to the application. Applications are sorted by Application ID in descending order by default. Application ID can be manually changed</td>
</tr>
<tr>
<td>Title</td>
<td>Title of the application</td>
</tr>
<tr>
<td>Status</td>
<td>Ethics application status</td>
</tr>
<tr>
<td>Primary Investigator</td>
<td>The name of the Primary Investigator associated with the Research Project</td>
</tr>
<tr>
<td>Process Stage</td>
<td>The name of the workflow process state that the application is currently in</td>
</tr>
<tr>
<td>Template</td>
<td>The name of the eForm template used for creation of the application</td>
</tr>
<tr>
<td>Application Date</td>
<td>The date the application was made</td>
</tr>
</tbody>
</table>
All columns can be sorted; the default sort order is by Application ID in descending order so that the most recently created applications appear at the top of the list.

To change the sort order:

4.2 Reviewing an application (ERP Member)

After a review request has been received via email, the application will appear in your ‘For Assessment Review’ list. Click on the Application Title to open the application to be reviewed.

Work through the screens to review the application and enter comments if applicable.

4.3 Viewing and entering comments

In some cases, Supervisors, Ethics Officer or the Human Research Ethics Committee members may require applicants to make an amendment to their project or clarify certain points. These comments can be related to the application as a whole (application comments) or relating to a specific section or question (page comments).

There are 2 types of comments that will be entered on an application. Panel members and Panel Chairs have different permissions for the comments functionality. Panel Members will only be able to enter ‘General Comments’, which are indicated by a white flag. It will then be the responsibility of the Panel Chair to consolidate the comments by all Panel Members, remove duplicates and change to Action Comments where appropriate. Action Comments are indicated by a red flag. The researcher will be required respond to Action Comments, but not to General Comments. (General Comments are used to make notes or observations about the application. No action is required.)

To ensure the applicant is aware of which question the amendment relates to by entering the question number, followed by the amendment text (e.g. A.1.10 Please amend your start date for data collection- data collection cannot commence until Ethics Approval has been granted. National Statement, 2007, p8.)
4.3.1 Comment Flags

Coloured flags are used to indicate that there are page level comments in areas of the application tree. There is a flag against each page that has comments and a flag against the section if there is a flagged page within it. The colour of the flag indicates the status and/or priority of the comment.

If there are multiple comments of various priorities on a page or section, the highest priority flag will be shown.

<table>
<thead>
<tr>
<th>Flag</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Red</td>
<td>A reviewer has entered an action comment on a page</td>
</tr>
<tr>
<td>Amber</td>
<td>The applicant has responded to the action comment</td>
</tr>
<tr>
<td>Green</td>
<td>The reviewer has resolved the action comment that the applicant has responded to</td>
</tr>
<tr>
<td>White</td>
<td>There is a general note on the page—no action is required</td>
</tr>
</tbody>
</table>

Once the applicant has responded to the red flags, the colour will change to orange. The Ethics Officers will then check the applicant’s response and resolve the action comment, which will change the flag to green. In cases where the Ethics Officer does not feel that the amendment has been responded to appropriately, the flag will stay yellow in colour. If a response is required to be checked by a Panel Chair, the application will be sent to the Chair who will check the yellow flags within the application and then advise the Ethics Officer if the application is approved or not.

4.3.2 Application Comments

Application comments refer to general comments relating to the application as a whole. These may be used by the applicant themselves, or by the reviewers.
An unsaved comment will not be saved when you close the comments dialogue box. Make sure you save your comment first.

Your comment will appear in the list with any other previously entered comments.

4.3.3 Page Comments

Page comments refer to comments relating to a specific page or question. Page comments are indicated by a coloured flag which is located beside the page it relates to. Comments that require action by the researcher are indicated by a red flag.

To access the Page Comment, click on the page the comment relates to and then click on the page comment icon.
4.3.5 Deleting a comment

It is possible to delete comments created in the current workflow. For example, if a comment was made by a reviewer and then reverted to the Ethics Officer, these cannot be deleted. This is indicated by the delete icon being greyed out.

To delete comments click on the delete icon.

4.3.6 Using Standard Phrases in Comments

Standard phrases are available to be used to set phrases that are frequently used in reviewing ethics applications. The phrases are available for reviewers to insert their comments.
4.4 Entering a Review Outcome (ERP Members)

Entering a review outcome indicates to the Ethics Officers whether the reviewer approves the application or if amendment is required. If amendments are required, the reviewer should enter an Action Comment for the section or question that needs to be changed, then select a Review Outcome of ‘Pending’.

Each Panel member should enter their review outcome and comments (if applicable). The Panel Chair should be the last to enter their review outcome so that they can review and consolidate the other Panel Member comments (if applicable). Once the Panel Chair has entered his/her review outcome, the Ethics Officers will be informed by email.

Select an application Outcome option from the drop down list, below is a table describing the functions of each of the statuses.

<table>
<thead>
<tr>
<th>Assessor Review Outcome</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approved</td>
<td>Used where the reviewer recommends that no amendments are required and more information is not required</td>
</tr>
<tr>
<td>Pending</td>
<td>Used where the reviewer recommends that amendments and/or more information is required</td>
</tr>
</tbody>
</table>

Click on the ‘Action’ Tab and then on ‘Enter and Submit my review of application’ once you have clicked on the phrase you would like to use, click ‘insert’ to add it to the text box for editing.

Once the text has been inserted, it may be edited to suit the reviewer’s comment.

Click the green arrow to save.
4.5 Reviewing an application (ERP Chair)

After the ERP Members have completed their review of the application, the ERP Chair will enter the outcome of the review. All of the reviews are listed in the Review Outcome section of the application, where the reviewers, review dates and outcomes are listed. Not Specified indicates the reviewer has not completed their assessment.

After the comments have been resolved from a reviewer perspective, the Chair will then consolidate the comments and enter their assessment of the application (for creation and viewing comments, please see section 4.3)

Select an application Outcome option from the drop down list, below is a table describing the functions of each of the statuses.

<table>
<thead>
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<th>Assessor Review Outcome</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approved</td>
<td>Used where the reviewer recommends that no amendments are required and more information is not required</td>
</tr>
<tr>
<td>Pending</td>
<td>Used where the reviewer recommends that amendments and/or more information is required</td>
</tr>
<tr>
<td>Rejected</td>
<td>Used where the reviewer recommends that the application should be rejected</td>
</tr>
</tbody>
</table>

After the ERP Chair has entered their Review Outcome, the status will change to ‘ERP Final Review’ and be sent to the Ethics Officer for action.
4.6 Reverting application to applicant for amendment

An email will be sent to the Ethics Officer once the ERP Chair has completed their review. In cases where the Review Outcome is ‘Pending’, the application will be sent back to the applicant by the Ethics Officer for amendments to be made.

4.7 ERP Chair Final Review

After the Ethics Officer has received the amendments back from the applicant (if applicable), they will send the application back to the ERP Chair for final review and approval.

If the ERP Chair is satisfied with the application, they may approve the application by clicking on the ‘Action’ tab and then selecting ‘Approve Application’

If more amendments are required, they can revert to the Ethics Officer for amendments.

The status will change to Reviewed and the system will generate an email to inform the Ethics Officer of the approved application.

The Ethics Officer will then be notified by email that the application has been reviewed and approve the application or revert it back to the applicant if required.
5. Printing Applications and associated information

Reviewers can print their application and any associated comments, if desired. It can be printed as a PDF or HTML. When using the print function to print an application (submitted or not), all questions and responses will appear in the printout. If a question has not been completed, this will also be indicated.

Click on the 'Reports' Icon

Select the document you would like to print (e.g. application or comments)

Select the format you would like to print (e.g. HTML or PDF)

Click OK
Pop-up blockers will need to be disabled for http://orion.acu.edu.au in order for the report to be generated as they appear in a new window.

To disable pop-up blockers (windows):

Select the menu option ‘Tools’ from the Menu Bar at the top of the screen, then ‘Pop-Up’ blocker, then ‘Pop-up blocker Settings’.

Add ‘http://orion.acu.edu.au’ to the address field and click ‘Add’.

MAC users will need to use a browser that is able to handle active content (i.e. not Safari).
6. Application Statuses

In Orion, the application status provides the researcher, ethics officer and reviewers with information about where the application sits within the application process. The status is easy to see at any time within the application itself or within the list of applications on the screen.

For new applications, the status will be updated automatically; depending on the function the user selects (e.g. submit, allocation of review panel members, etc). In most cases, these events will also automatically generate an email to a predefined recipient (e.g. the ethics officer will be email once an applicant submits an ethics application).

Below is a table of Statuses in Orion and Significant Dates in RMEWIN and their definitions:

<table>
<thead>
<tr>
<th>Status/Date</th>
<th>Significant Date</th>
<th>Workflow Branch</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Applicant Submitted</td>
<td>High &amp; Low Risk</td>
<td>Applicant Submitted Application</td>
<td></td>
</tr>
<tr>
<td>Initial Panel Review</td>
<td>High &amp; Low Risk</td>
<td>Student submitted application, Ethics Officer allocates the student’s supervisor to review</td>
<td></td>
</tr>
<tr>
<td>Revisions</td>
<td>High &amp; Low Risk</td>
<td>Acknowledgement of application, Ethics Officer sends amendment request to applicant prior to Panel/HREC review</td>
<td></td>
</tr>
<tr>
<td>Amendment Received</td>
<td>High &amp; Low Risk</td>
<td>Researcher makes requested amendments and submits to Ethics Officer</td>
<td></td>
</tr>
<tr>
<td>ERP</td>
<td>Low Risk</td>
<td>Ethics Officer reviews the application and allocates Expedited Review Panel(s) (ERP)</td>
<td></td>
</tr>
<tr>
<td>ERP Final Review</td>
<td>Low Risk</td>
<td>ERP member(s) check and submit application back to Ethics Officer</td>
<td></td>
</tr>
<tr>
<td>Memo</td>
<td>Low Risk</td>
<td>Ethics Officer sends a memo to researcher after ERP review for amendments</td>
<td></td>
</tr>
<tr>
<td>Chair Review</td>
<td>Low Risk</td>
<td>Ethics Officer reviews ERP member approval and sends to ERP chair</td>
<td></td>
</tr>
<tr>
<td>Reviewed</td>
<td>Low Risk</td>
<td>EPC reviews the application and approves</td>
<td></td>
</tr>
<tr>
<td>Approved</td>
<td>High &amp; Low Risk</td>
<td>Ethics Officer confirms approval of application</td>
<td></td>
</tr>
<tr>
<td>HREC</td>
<td>High Risk</td>
<td>Acknowledgement of application- Ethics Officer refers the application to HREC</td>
<td></td>
</tr>
<tr>
<td>Chair Review</td>
<td>High Risk</td>
<td>Ethics Officer forwards application to HREC chair- application approved in HREC meeting</td>
<td></td>
</tr>
<tr>
<td>Memo</td>
<td>High Risk</td>
<td>HREC reviewed application and amendments required</td>
<td></td>
</tr>
<tr>
<td>Rejected</td>
<td>High &amp; Low Risk</td>
<td>Project rejected by HREC/ERP as required changes were not considered/made</td>
<td></td>
</tr>
<tr>
<td>Withdrawn</td>
<td>High &amp; Low Risk</td>
<td>Project withdrawn by applicant prior to approval by ERP/HREC</td>
<td></td>
</tr>
</tbody>
</table>