

# Themis Human Ethics



## Introduction to Themis Human Ethics

### What is Themis Human Ethics?

Themis is an integrated administration system used by all staff at the University to perform functions related to their role. The Themis system services the business areas of Human Resources, Research and Finance.

The Themis Human Ethics module provides access to create and submit an application for human ethics approval, as well as to progress it through the required committee approval process.

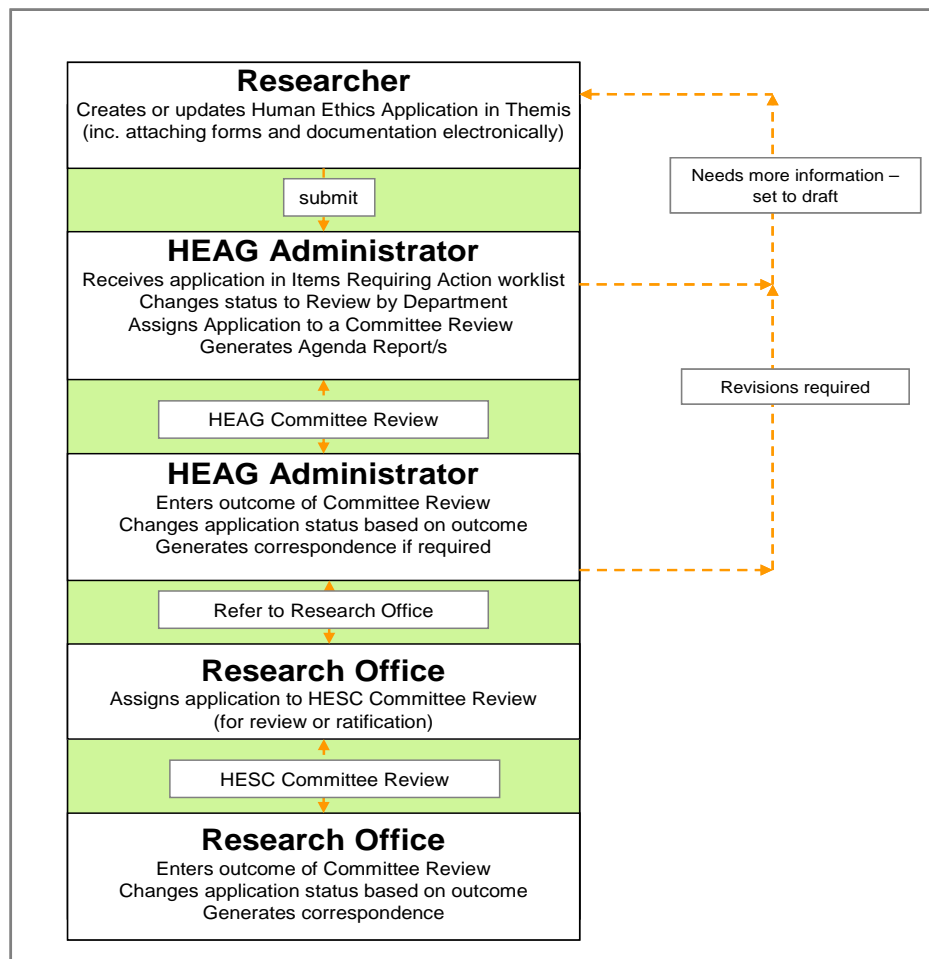
The Themis Human Ethics module is used by:

- **Researchers** (staff and research-active students) to register, submit and track ethics applications, and related annual reports.
- **Human Ethics Advisory Group (HEAG) and Research Office administrators** to administer ethics applications, initiate standard correspondence, and prepare reports for consideration by Human Ethics Advisory Groups (HEAGs) and/or Human Ethics Sub-Committees (HESCs).

### Themis Human Ethics Application Process Overview

An overview of the human ethics application process is outlined in the diagram below. The creation process for a human ethics application can be initiated by either the researcher or by the HEAG Administrator on behalf of the researcher.

**Note:** once a human ethics application is submitted, the researcher will be unable to make changes to the application and can access the application via the Human Ethics Workbench as view only.



## Components of the Themis Human Ethics module

The **UOM RMS Human Ethics Department** responsibility (used by HEAG administrators) contains three separate components of the Themis Human Ethics module: Ethics, Common Modules and Reporting.

Each component contains links to discrete functions within the module:

| Component      | Link                         | Function description  |
|----------------|------------------------------|---|
| Ethics         | Human Ethics Admin Workbench | The Administration component of Themis Human Ethics. This link allows HEAG Administrator or Research Office staff to receive human ethics application/s and administer the application/s through the committee review process.<br>Functions include: <ul style="list-style-type: none"> <li>• Status Management</li> <li>• Document Review</li> <li>• Correspondence</li> <li>• Reporting</li> </ul>  |
| Ethics         | Human Ethics Workbench       | The primary Researcher component of Themis Human Ethics. This link allows Researchers (or HEAG Administrators/Researcher Office) to: <ul style="list-style-type: none"> <li>• Create a human ethics application</li> <li>• Register or transfer an ethics application</li> <li>• Search and monitor existing applications</li> <li>• Update applications as required</li> <li>• Submit annual reports</li> </ul>  |
| Common Modules | Committee Management         | The component of Themis Human Ethics for administering Human Ethics Committees.<br>This link allows Research Office staff to create Human Ethics committees, assign departments, members, roles and end dates to these committees.<br>HEAG Administrators use this sub-module to administer the HEAG committee on which they are named as Administrator or Alternate Administrator including: <ul style="list-style-type: none"> <li>• Modify member details (including: add/delete members)</li> <li>• Assign committee roles</li> </ul> |
| Common Modules | Meeting Management           | The component of Themis Human Ethics for administering Human Ethics Committee meeting schedules.<br>This link allows Research Office staff to create and modify meetings schedules for all Human Ethics committees.<br>HEAG Administrators use this sub-module to create and maintain the meeting schedules for the HEAG committee on which they are named as Administrator or Alternate Administrator.   |
| Reporting      | Reporting                    | The Reporting component of Themis Human Ethics. Reports available include: <ul style="list-style-type: none"> <li>• Printable versions of Themis Human Ethics applications and annual reports</li> <li>• Correspondence</li> <li>• Agenda and Outcome Reports</li> <li>• General Reports (including by application status and document type)</li> </ul>   |
| Reporting      | Annual Report by Status      | Run reports relating to annual reports. Parameters include: <ul style="list-style-type: none"> <li>• Annual Report Year</li> <li>• HEAG</li> <li>• Department</li> </ul>  |

## Themis Human Ethics troubleshooting

### Committee management

If you are going to be away for a short period you may like the Alternate Administrator of the HEAG to be notified when any new human ethics applications are lodged.

There are two ways to achieve this. The first is that the alternate administrator may simply search for any human ethics applications with an Operational Status of *Lodged*.

However, if you wish the alternate administrator to be able to view the applications via the Item Requiring Action screen and be notified by email each time a new application is lodged, you will need to give them the role of *Administrator* for the period you are away.

To change the Administrator:

- 1 Retrieve the appropriate HEAG record and navigate to the Member Details screen.
- 2 Click on the **Show** link next to your name and change your role from *Administrator* to *Alternate Administrator*.

| Membership |         |                      |             |                            |
|------------|---------|----------------------|-------------|----------------------------|
| Select     | Details | Member Name          | Member Type | Department/Organisation    |
|            | Show    | Cattle, Prof Brandon | Staff       | University Systems Project |

- 3 Click on the **Show** link next to the Alternate Administrator's name and change their role to *Administrator*.
- 4 Click on the **Save** button to save your changes.

### Administering a human ethics application

#### Data missing from the Minimal Risk Approval Letter

When a HEAG committee has approved a Minimal Risk project you will need to retrieve the application and set the Status to *Approved*. Once the status has been updated, you may print a Minimal Risk Approval Letter (via the **Reporting** tab) and send it to the researcher.

At this stage you may, find the letter does not contain the relevant data for the project. To ensure the letter has the required data:

- 1 Navigate to the *Application Management* section of the application and check the latest Document Review record:
  - Has it been prepared for a committee meeting? If not, prepare a new document review and set it to the scheduled meeting date.
  - Has the scheduled meeting date arrived or passed? As the HEAG has approved the project the Committee should have already met.
  - Has the Document Review Outcome field been set to *Approved*? If not, update the field to *Approved*.
- 2 Once you have checked/updated the document review record, you can re-select the Minimal Risk approval letter via the **Reporting** tab.

The letter should now include relevant details about the project.

#### Updating the status of amendments (or projects) following a HEAG meeting

To prevent researchers chasing you regarding the outcome of amendments they have submitted for HEAG review, we recommend you update the record status in Themis as early as possible following the HEAG meeting.

Once the HEAG has agreed that an amendment is ready for an ethics committee review, the administrator should change its status to *Refer to Research Office*, and ensure that a signed paper version (plus one copy) is sent to the Research Office.

**Note:** this situation is similar for a Minimal Risk application. In this case, you should update the status to *Approved HEAG* and ensure that a signed paper version complete with approval letter (plus one copy) is sent to the Research Office.

## The brief description displayed on the front page of the application is incomplete

The brief description that displays on the front page of an application summary report should be limited to 100 words. Many researchers exceed this word limit, and while there is capacity in the relevant Themis field to do this, the application summary report will not display any additional text.

To update a description to display the full text:

- 1 Open two web browser sessions.
  - In the first browser - locate the relevant Application Summary Report (RTF format) via the **Reporting** tab.
  - In the second browser - locate the relevant application via the **Search** function and navigate to the Application Summary screen and copy the text in the Brief Description field.
- 2 Return to the browser that displays the Application Summary Report.
- 3 Highlight the incomplete text and paste the text from your clipboard.
- 4 Reprint the report, which should now have the complete project description on the front page.

## Processing a Registration application

A Registration is used when a project which includes University of Melbourne researchers has been approved by an ethics committee external to this University, and where the external committee maintains responsibility for the entire project. The appropriate HEAG needs to check this approval and ensure that the roles undertaken by local researchers are clear.

For further details, including the documents researchers need to provide, refer to **Creating a Registration of External Ethics Clearance** ([http://www.themis.unimelb.edu.au/resources/RC\\_Human\\_Registration\\_External.pdf](http://www.themis.unimelb.edu.au/resources/RC_Human_Registration_External.pdf))

Administering a registration on Themis is the same as administering a Standard Project:

- 1 Progress the registration through the appropriate status levels until you reach *Refer to Research Office*.
- 2 Click the **Save** button to save the status.
- 3 Send a hard copy of the application (with HEAG signature on the front) to the Research Office.  
The Research Office will provide the researcher with a registration letter (note: this is not an approval letter).

## Student access to Themis Human Ethics

A student researcher has been advised that the project they are doing requires human ethics approval, however, they cannot access Themis and ask you to help.

- If the student is a postgraduate, they should have access to Themis. You could refer them to the Themis Service Desk ([themis-help@unimelb.edu.au](mailto:themis-help@unimelb.edu.au)) for assistance with gaining access.
- If the student is an undergraduate, you will need to send a request to a Human Ethics staff member at the Research Office to set the student to *Research Active* status.

Once access has been granted, the student may set up/activate their Themis account via the Accounts Registration System <http://accounts.unimelb.edu.au>.

Further details on creating a Themis account are available on the *Themis - New user information* page [http://www.themis.unimelb.edu.au/starting/new\\_user.html](http://www.themis.unimelb.edu.au/starting/new_user.html).

# University of Melbourne – Human Ethics Policy

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## When is human ethics approval needed?

*Human research* has a broad definition and includes research conducted with or about people, or their data or tissue. You need ethics approval if you are a University staff member or a postgraduate student and want to conduct certain research activities involving humans. These include, but are not restricted to:

- Gathering information about human beings (and organisations) through interviewing, surveying, questionnaires, observation of human behaviour, audio/video taping, administering tests or stimuli, collecting or using human tissue/bone/blood or other body fluids.
- Clinical trials.
- Using archived data in which individuals are identifiable.
- Study or research in illegal activities.

## Human Ethics Advisory Groups (HEAGs)

The primary function of a Human Ethics Advisory Group (HEAG) is to provide preliminary assessment of human research projects submitted by staff and students in a department, school or faculty; and to advise the relevant Human Ethics Sub-Committee (HESC) and the central Human Research Ethics Committee (HREC) on issues pertaining to human research ethics in the department, school or faculty.

For policy information regarding HEAGs refer to the Melbourne Research Office website:

<http://cms.research.unimelb.edu.au/humanethics/membersadmins/roles/heag>

## Getting help

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The Themis website ([www.themis.unimelb.edu.au](http://www.themis.unimelb.edu.au)) provides written support in a variety of formats:

- Reference cards (step-by-step instructions for specific tasks)  
[http://www.themis.unimelb.edu.au/support/ref\\_cards.html](http://www.themis.unimelb.edu.au/support/ref_cards.html)
- Information sheets (overview of specific module, function or responsibility)  
[http://www.themis.unimelb.edu.au/support/documentation/info\\_sheets.html](http://www.themis.unimelb.edu.au/support/documentation/info_sheets.html)
- Frequently Asked Questions <http://www.themis.unimelb.edu.au/support/faq.html>

## Themis Service Desk

The Themis Service Desk team provides technical assistance from 9am to 5pm, Monday to Friday. You may lodge Themis queries:

Online: <http://servicedesk.unimelb.edu.au/itsc/themis>

By email: [ea-help@unimelb.edu.au](mailto:ea-help@unimelb.edu.au)

By phone: 8344 9500