

Any human ethics application that has been approved or ratified by the HESC (in a system status of finalised) has annual reporting obligations. You will receive an email notification advising that an annual report is due and any application with a report due will display in the Annual Reports Due section of the Responsible Researcher's Human Ethics Workbench.

Completing an annual report

- 1 Log in to Themis using the **UOM Research Self Service** responsibility.
- 2 Select the **Human Ethics Workbench** function listed under the Ethics section.

The Human Ethics Home Page - Researcher Worklist screen will display. The Annual Reports Due section will display a list of applications with a report due. **Note:** Co-researchers and students may lodge an annual report by accessing the record via the Current Application section and clicking on the **Update** button in the Ethics Record Overview screen.

Ethics Id	Application Type	Responsible Researcher	Title	Update
0600380.3	Minimal Risk	RONI, DR PEPE	The best things about pizza	

- 3 Locate the required application and click on the **Update** icon.

The Annual Report Details screen will display. This screen is the first in a series of steps required to complete the annual report process. **Note:** this screen is view only - if you wish to update any details on this screen you will need to send an email to the relevant HESC Administrator.

Step 1 - Annual Report Details Cancel Save Step 1 Next

Ethics Application ID	Approval Category	Application Type	Maximum Expiry Date	Annual Report Number	Year
0600380.3	HEAG	Minimal Risk	22-Sep-2011	1	2006

Project Title
The best things about pizza

Researcher/Department details
If any changes have been made to the researchers associated with the research as outlined below (including the Department with which they are associated, or their contact details), note that you will need to submit a separate Request for Amendment.

Researcher Role	Researcher Type	Researcher Name	Department/Organisation
Responsible Researcher	Staff	Roni, Dr Pepe	018 - University Systems Project
Co researcher	External	Aido, Professor Tom	Pizza Hut Pty Ltd

- 4 Click on the **Next** button.

The Annual Report Project Status screen will display.

Specify the status of the project

The Annual Report Project Status screen allows you to indicate the current status of the research project and provide any details regarding the progress of the project. **Note:** it is recommended that, while completing your annual report, you save regularly to ensure you do not lose information if your session times out.

Step 2 - Annual Report Project Status Cancel Save Back Step 2 Next

Status of project

Please indicate the current status of the project: Continuing - data collection not yet complete

Estimated completion date

Please indicate the anticipated completion date: 28-Feb-2007

Project Progress

Please give a BRIEF statement of progress in the project to date or please explain why project was abandoned or, in the case of a completed project the outcome of the research.

- 1 Enter the status details for the project.

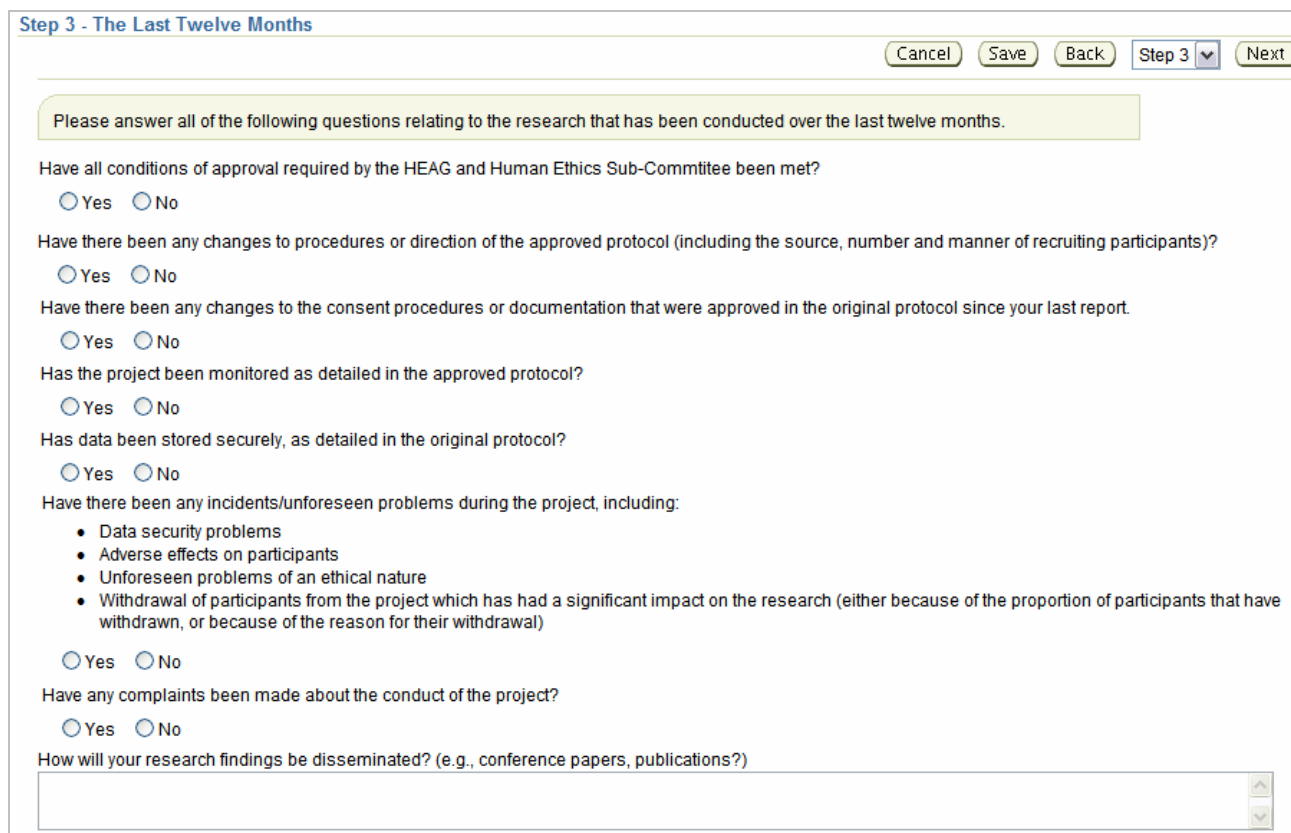
Field	Action	Comments
Current status of project	Select the appropriate status from the drop-down list	If you select a status of Not yet commenced or Continuing - Data collection not yet complete you will need to indicate an anticipated completion date for the project.
Estimated completion date	Enter the anticipated completion date for the project	Note: this field will only display if you select Not yet commenced or Continuing - Data collection not yet complete in the status field above.
Project progress	Enter a brief statement regarding the project process to date, or reasons the project was abandoned	

2 Click on the **Next** button.

The Last Twelve Months screen will display.

Indicate the progress of the research conducted over the last 12 months

The Last Twelve Months screen enables you to answer a number of specific questions regarding the progress of the research conducted over the preceding 12 months.



Have all conditions of approval required by the HEAG and Human Ethics Sub-Committee been met?

1 Click on the appropriate radio button to indicate whether the conditions of approval have been met.

Note: if you select **No** you will need to complete additional information that will display below.

- Enter the details of the conditions that have not been met and reasons why.

Have there been any changes to procedures or direction of the approved protocol?

2 Click on the appropriate radio button to indicate whether the approved procedures or direction have changed.

Note: if you select **Yes** you will need to complete additional information that will display below.

- Enter the details of the procedures or direction that have changed.
- Indicate whether approval has been sought for these changes by selecting Yes or No from the drop-down list.

Have there been any changes to the consent procedures or documentation that were approved in the original protocol?

3 Click on the appropriate radio button to indicate whether the consent procedures or documentation have changed.

Note: if you select **Yes** you will need to complete additional information that will display below.

- Enter the details of the consent procedures and/or documentation that have changed.

Has the project been monitored as detailed in the approved protocol?

4 Click on the appropriate radio button to indicate whether monitoring has been performed as detailed in the protocol.

Note: if you select **No** you will need to complete additional information that will display below.

- Enter the details of the monitoring that has been performed and why it was not conducted as outlined in the approved protocol.

Has data been stored securely, as detailed in the original protocol?

5 Click on the appropriate radio button to indicate whether the data has been stored as detailed in the protocol.

Note: if you select **No** you will need to complete additional information that will display below.

- Enter the details of the data storage undertaken and why it has not met the approved protocol.

Have there been any incidents/unforeseen problems during the project?

6 Click on the appropriate radio button to indicate whether there have been any incidents/unforeseen problems.

Note: if you select **Yes** you will need to complete additional information that will display below.

- Enter the details of the incidents/problems.

Have any complaints been made about the conduct of the project?

7 Click on the appropriate radio button to indicate whether there have been any complaints regarding conduct.

Note: if you select **Yes** you will need to complete additional information that will display below.

- Enter the details of the complaints and the action taken by researchers.

How will your research findings be disseminated?

8 Enter the details of the methods by which the research finding will be disseminated.

9 Click on the **Next** button.

The Continuing Projects screen will display.

Complete the continuing project details

This screen enables you to confirm that the correct process details are in place for continuing projects. **Note:** this screen need only be completed if you select a project status of **Not yet commenced** or **Continuing - data collection not yet complete**.

Step 4 - Continuing Projects

Do you propose to make any amendments to the project including SIGNIFICANT changes to the plain language statement(s) and consent form(s) that will need approval for use in the coming year?

Yes
 Not required
 Yet to be determined

If 'YES' you will need to submit a Request for Amendment to your HEAG before new work can proceed. This can be done by completing and submitting your request via Themis Research.

Have you reviewed (and updated where necessary) all current advertisements, plain language statements and consent forms to be used in the coming year? (e.g., dates, names and contact details of researchers, etc.)

Yes, relevant document have been updated/are current

Can you please confirm that the relevant contact details for the HREC are included in documentation to be provided to participants

Yes, relevant documents include current contact details for the approving HREC

Note that it is a requirement of approval that participants be provided with contact details for the approving HREC. These details should be included in any plain language statements or other documentation provided to participants. (Note that the relevant contact number for the Executive Officer, HREC, at the University of Melbourne is 8344 2073.)

Please confirm that all people or groups (for example, coresearchers, research assistants, schools, hospitals, organisations) involved in recruitment been instructed in the informed consent procedures approved by the approving HEAG/HESC?

Yes, people/groups involved in recruitment have been instructed in informed consent procedures
 Not Applicable

Do you propose to make any amendments to the project that will need approval for use in the coming year?

1 Click on the appropriate radio button to indicate whether amendments requiring approval will be made.

Note: if you select **Yes** you will need to submit a Request for Amendment to your HEAG before any new work may proceed. For further details refer to the **Request for amendment of a Human Ethics application** information sheet.

Have you reviewed all current advertisements, plain language statements and consent forms to be used in the coming year?

2 Tick the checkbox to confirm the relevant documents are current or have been updated.

Note: if you do not tick this box, you will receive an error at the validation stage.

Please confirm the relevant contact details for the HREC are included in documentation to be provided to participants.

3 Tick the checkbox to confirm the HREC contact details are included in participant documentation.

Note: if you do not tick this box, you will receive an error at the validation stage.

Please confirm that all people or groups involved in recruitment have been instructed in the informed consent procedures approved by the approving HEAG/HESC?

4 Click on the appropriate radio button to indicate whether the involved people/groups have been instructed in informed consent procedures or that this is not applicable.

Note: if you do not select an option, you will receive an error at the validation stage.

5 Click on the **Next** button.

The Other Comments screen will display.

Enter any additional comments

The Other Comments screen enables you to include any additional comments related to your research.

Step 5 - Other Comments

Other Comments

Please include any additional comments you may wish to make regarding this research.

1 Enter any comments regarding your research project, if applicable.

2 Click on the **Next** button.

The Annual Report Review screen will display.

Review the annual report

The Annual Report Review screen will identify any validation errors or omissions (e.g.: you have not entered dissemination details for your research findings) in relation to your annual report.

If validation errors are identified

Step 6 - Annual Report Review

Annual Report Review

Data validation errors have been identified in this annual report. You cannot proceed to the submission page until the errors specified in the table below have been corrected.

Data Validation Error	Application Step	Go To Page
Details regarding how your research findings will be disseminated have not been entered	Step 3	

1 Click on the associated icon in the Go To Page column.

This will link you directly to the appropriate page.

2 Update the information as required and click on the **Save** button to commit your changes.

3 Use the drop down list () at the top or bottom of the screen to return to the review page.

4 Repeat the steps above for each of the validation errors.

5 Click on the **Next** button.

The Annual Report Submission screen will display.

Submit the annual report

Once you have reviewed your annual report and corrected any validation errors, you may submit it.

1 Read the submission confirmation statement.

2 Tick the checkbox to the right of the statement.

Note: you will be unable to submit the report until you tick this box (i.e.: the **Submit Annual Report** button will not be active).

3 Click on the **Submit Annual Report** button.

A Confirmation of Submission screen will display.

Step 7 - Annual Report Confirmation

Ethics Application ID	Year	Date of submission	Application Type
0600380.3	2006	22-Feb-2007	Lodged

Title: The best things about pizza

Researchers:

Name	Researcher Type	Researcher Role	Department/Organisation
Roni, Dr Pepe	Staff	Responsible Researcher	018 - University Systems Project
Aido, Professor Tom	External	Co researcher	Pizza Hut Pty Ltd

Annual Report Confirmation

Thank you for submitting the annual report for the above project. An email has been sent to all named researchers advising that the annual report has been submitted.

Note that when the annual report has been approved an email will be forwarded to all researchers confirming that the project has either continuing approval or is no longer active.

Important: once submitted, the Annual Report will no longer display in the Annual Reports Due table of your Workbench. If you wish to view the annual report, you may do so by searching for the appropriate Ethics Application (or accessing it via your Current Applications table) and navigating to the Annual Reports screen.