Completing a Human Ethics Annual Report

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 named researchers’ Human Ethics Workbench.

Completing an annual report

1. Log in to Themis using your 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.

   ![Annual Reports Due Table]

3. Locate the required annual report 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.

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.
1. Enter the status details for the project.

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

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/unforseen problems during the project?

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

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 reference card*.

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.

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

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.

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.