December Ethics Studio:

Reporting and Finishing the Project

Terry Bowles PhD FAPS CEDP CCLIN

Room L207, 100 Leicester St Carlton | P: +61 3 8344 9638 | F: +61 3 9348 2753 |
M:0448 056 039 | E: tbowles@unimelb.edu.au |
The Aim of today’s session is to better understand the

• elements of the ethics process and where the annual report fits
• aims of the annual report
• authority that requires an annual report
• what will trigger the report
• what the report looks like
• what happens if…
Elements of the Ethics Process at MGSE

- Application
- Review by the local HEAG
  - Feedback
  - Response
- Approval/Review by the HESC
  - Feedback
  - Response
- Approval
- Research Activity (for duration of research – years?)
- Review of Activity – ‘Annual Review’
• What happens after the research is approved? 
  ….what stories have you heard?

• Drift… opportunity… error

• To ensure that
  • Research is conducted as approved (stay on track)
  • Research is conducted ethically (‘stays ‘legit’”)

• …..Annual Report
Chapter 5.5: Monitoring Approved Research

5.5.5 At regular periods – reflecting the degree of risk, and at least annually and at the completion of the project – researchers should provide reports to the relevant review body/ies and institution/s, including information on:

(a) progress to date, or outcome in the case of completed research;
(b) maintenance and security of records;
(c) compliance with the approved proposal; and
(d) compliance with any conditions of approval.

(National Statement Guidelines, NHMRC, 2007/2018, p. 96)
An annual review is

• a response to a series of questions

• generated on Themis

• specifically related to registered projects
The National Statement on Ethical Conduct in Human Research requires Human Research Ethics Committees to monitor all research projects that have received ethics approval. This is to ensure that work being undertaken is in accordance with the approved protocol and that the rights and interests of those who have consented to take part as participants are protected. As part of the monitoring process University researchers are to provide an annual report on projects for which they have ethics approval.

Annual Reports are now due for all projects that are to continue in {4} or were completed or abandoned in {5}.

Reports should be submitted on-line via Themis by the due date of {6}.

Any researcher who has been named on the project who is a current University staff member, honorary staff member or student will be able to submit the Annual Report. It is the role of the Responsible Researcher to ensure that the Annual Report is submitted by the due date.

Researchers can access Themis at http://www.themis.unimelb.edu.au. You will see the Annual Report on your Human Ethics Workbench under the heading 'Annual Reports Due'. Click on the 'Update' icon to submit the report on-line.

For queries about accessing Themis contact the IT Service Desk ph 8344 0888. If you have not accessed Themis before, you will first need to create a Themis password at https://staff.unimelb.edu.au/informationtechnology/accounts-and-passwords or https://accounts.unimelb.edu.au/manage/login.jsp


Manager
Human Research Ethics
Research Ethics & Integrity
What is the Process?

You will receive a reminder requesting you complete a review:

1. Log in to Themis.

2. Select ‘human ethics workbench’.

3. Locate the annual report required. Click ‘update’. The ‘annual report details’ screen will display. It is view only.

4. Click ‘next’. The ‘annual report project status’ screen will display. This allows you to indicate the current status of the research and provide any details regarding the progress of the project. Save your work regularly when completing annual reports, in case your session times out.

5. Enter the status details for the project.

6. Click ‘next’. The ‘last twelve months’ screen will display. This enables you to answer a number of specific questions regarding the progress of the research you have conducted in the previous twelve months.

7. Answer the ‘last twelve months’ questions, including details when prompted.
You will receive a reminder requesting you complete a review (cont.):

8. Click ‘next’. The ‘continuing projects’ screen will display. This enables you to confirm that the correct process details are in place for continuing projects. You only need to complete this screen if you select ‘not yet commenced’ or ‘continuing – data collection not yet complete’ as your project status.

9. Answer the ‘continuing projects’ questions.

10. Click ‘next’. The ‘other comments’ screen will display. This enables you to include any additional comments related to your research.

11. Enter comments, if applicable.

12. Click ‘next’. The ‘annual report review’ screen will display. This lets you identify any validation errors or omissions in relation to your annual report.

13. If there are validation errors, click on the ‘go to page’ icon in the ‘go to page’ column. This will link you directly to the appropriate page.

14. Update the information as required and click ‘save’ to commit your changes.
• …change to improve the research along the way…

  – Apply for an amendment
Jan is doing research on adolescents in secondary schools. The research team sought ethical approval to gather data from students at years 8, 10, and 12. Unfortunately, the week that they were gathering data from students there was a year eight camp. The campus coordinator suggested that the data be gathered from year 6 and 7 students and arranged for the PLS and consent form to be sent to parents and students at this level. The staff cooperatively distributed the questionnaires during class and gathered the data.
• What happens next, if…?

• … A father of one of the students, when picking up their child is told of the research that the child completed that day. On going home the parent reads the PLS that is on the table stating that only students in year 8, 10 and 12 will be surveyed. The parent contacts the Office for Research Ethics and Integrity, University of Melbourne and the school, complains vigorously and asks that the students questionnaire be returned immediately as the consent form was signed by students grandmother who thought she ‘was doing the right thing’.

or

• … After the questionnaires are taken back to the University and are being looked at by the Principal Researcher, they realise that there is a problem…

or

• … As the student researchers who are working on the project, begin to complete the annual review, they realise that the ethics application only approved students in year 8, 10 1nd 12 to complete the questionnaire.
In summary, what we did was to discuss:

• where the annual report fits
• the aims of the annual report
• the requirements of the National Statement (NHMRC)
• the process of reporting
• completing the report
• what happens if there is a breach of the approved research project
Thank you