ERM Animal Report Subform guidance

Introduction

This document is a guide to completing the Animal Ethics Report subform in QUT's Ethics Research Manager (ERM). It's purpose is to help you understand each question, and therefore to help you consider and explain how you have cared for the animals you have used in your project.

About the form

The subform is used for all types of animal reports, including those required as specific conditions of your project approval, annual progress reports, project final (completion) reports or any additional report you are requested to submit to the University Animal Ethics Committee (UAEC). You can also use this form if you would like to submit any additional updates on your project to the UAEC (i.e. that weren't requested as a condition of your approval).

To generate the animal report subform in ERM, first select the project you are reporting on. Then in the left hand column click 'create subform', select 'animal report form' then click 'create'.

The form is a 'dynamic' document, and questions may appear or disappear depending upon how you have responded to a previous question. As such, the numbering adjacent to each question may not seem to be consecutive.

It is important for you to remember the composition of the UAEC when completing the form. **Reports should be written in lay language primarily for an interested, intelligent person without a scientific background, not for a specialist.** Your report should clearly describe what happened to the animals and what was done to ensure their well-being. Your report should also address the 3Rs (Replacement, Reduction and Refinement) wherever appropriate.

Documents can be uploaded to the form in most standard formats (e.g.word, excel, pdf, jpeg, mp4 etc). The form does not support hyperlinks. NOTE: the maximum total upload size for the whole project is 10GB, therefore if you want to include a lot of large files (particularly videos) you should type in the web address for a file sharing system.

Once you have answered all the questions you can choose to perform a 'completeness check' to identify any sections in the form you may have missed. Most question on the form are compulsory, however it is possible to write 'not applicable' in response to a question if the content requested does not suit your report.

The form automatically saves each time you select 'next' to move between sections. You can also 'save' your form as you go if you're not able to complete it at once, or if you want your project collaborators to review your responses prior to submission.

What happens next?

When you've completed the form, sign the declaration and select 'submit' to send the form to the animal ethics team.

Once submitted, your report subform will initially be assessed by the Animal Welfare and Ethics Coordinator (AWEC) then sent to the UAEC for review. You will receive an email notification if the AWEC or the UAEC have any additional questions about the report, if any further action is required, or if your project is approved to continue.

Once your final (completion) report is approved by the UAEC, the project will be closed off in the ERM system.

Additional resources

It is recommended that you review the following guidelines (also referenced in this document) before preparing your report:

- The Australian Code for the care and use of animals for scientific purposes (the Code)
- Best practice methodology in the use of animals for scientific purposes
- PREPARE: guidelines for planning animal research and testing
- Improving Bioscience Research Reporting: The ARRIVE Guidelines for Reporting Animal Research

Guidance by question

Project details

1.1 Current Project Chief Investigator	Enter the name, phone and email details for the project Chief Investigator
1.2 Report Author	Provide your name and best phone and email contact details

Current Project Status

2.1 Are you submitting a report or responding to a Specific Condition of your ethics approval? • Final/Annual Progress report • Response to Specific Condition(s) of Approval • Other report	*This question helps decide the type of report, and therefore which sections of the form you will be asked to complete.* Select 'other report' if you are providing a report that was not a condition of your project's approval, or if you are providing an update on your project that was not requested by the UAEC, or was requested as the project progressed.
2.2 I understand that I am reporting on the Project's status and activities that have occurred in the CALENDAR YEAR which finishes 31 December	*This question will only appear for annual progress and final reports.* You should select the calendar year you are reporting on.
2.3 What was the status of the project on 31 December in the year selected in question 2.2? • Not commenced and abandoned • Not yet commenced • Commenced and abandoned • In Progress • Complete	*This question will only appear for annual progress and final reports.* • *If you select 'Not commenced and abandoned' only question 2.4.4. will appear.* • *If you select 'Not yet commenced' questions 2.3.1 and 2.4.1 will appear.* • *If you select 'Commenced and abandoned' question 2.4.4. will appear and the form will become will become your project's final/completion report (questions 3.1B to 3.10B and question 5.1 will appear).* • *If you select 'In progress' question 2.4.1 will appear and the form will become an annual progress report (questions 3.1A to 3.6A and question 5.1 will appear).* • *If you select 'Complete' the form will become your project's final/completion report (questions 3.1B to 3.10B and question 5.1 will appear).*

2.3.1 Please explain why this project has not yet commenced.	*This question will only appear if you selected 'not yet commenced' in question 2.3.* Describe why you have not started your project. Examples could include personnel or equipment issues, funding, environmental factors, waiting on grant funding etc.

2.4.1 Would you like to request an extension?
   • Yes
   • No
	This question will only appear if you selected 'not yet commenced' or 'In Progress' in question 2.3.
	
	If you select 'yes' questions 2.4.2 and 2.4.3 will appear.

2.4.2 If you require an extension, what is your new anticipated end date?	List the new date you expect the <u>live</u> animal work on your project will end. An extension might not be required if you are only analysing the data or the tissue samples from your project, unless you anticipate you may need to conduct more live animal work at some stage to obtain additional information. NOTE: standard animal ethics approval is 3 years and approvals can only be extended to a maximum of 5 years at which stage a full resubmission of the application is required.
2.4.3 Please justify the need for an extension.	You should briefly explain why you need more time to complete the project and if this has any potential impact on the wellbeing of the animals involved or on the project as a whole (e.g. an extension could introduce variables in animal groups). When requesting an extension you should use it as an opportunity to reconsider how you have applied the 3Rs (replacement, reduction, refinement) to your project and describe if any changes to the project are necessary. If you propose to make changes to the project you will also need to submit a variation request in ERM and update the application accordingly. The project extension and any changes to the project need to be approved by the UAEC before they are implemented.
2.4.4 Please explain why the project did not go ahead or proceed.	*This question will only appear for projects that were 'not commenced and abandoned' or 'commenced and abandoned'.* *For 'not commenced and abandoned' projects, once you have completed this question the form will go directly to the declarations section.* *For 'commenced and abandoned projects' you will need to complete questions 3.1B to 3.10B and question 5.1.* Describe why the project was abandoned including any alternatives you considered to allow you to complete the project. Examples could include personnel or equipment issues, funding, environmental factors, waiting on grant funding, animal model not working as anticipated etc.

For projects that were commenced but terminated early, briefly outline how far the project had progressed before it was abandoned. Were you able to achieve any of the project's aims? You should also describe if there was any 'wastage' of animals as a result of finishing the project early.

Other Report

This section (questions 2.1R and 2.2R) will only appear for 'other' reports.

2.1R Please upload your other report	This could be a written report, additional lab results, images, animal monitoring sheets etc.
2.2R Please provide any notes or additional information associated with this other report.	You should explain why you are submitting this report, paying particular attention to how the activities discussed in the report impacted the wellbeing of the animals involved. If you wish to provide any videos or other large files it is preferable to provide a link to a file sharing system (e.g. Onedrive)

Specific Conditions of Approval Report

This section (questions 2.1S to 2.3S) will only appear for 'response to specific conditions of approval' reports.

2.1S Please identify the specific condition you are reporting on.	Copy and paste the details of the specific condition you are reporting on from your project ethics approval email.
2.2S Please provide any notes or relevant information on the specific condition.	You should directly address any criteria requested by the UAEC. Your response should explain how the activities conducted impacted the wellbeing of the animals involved. Alternatively you can attach your report as a word document (or similar) in question 2.3S.
2.3S Please upload any supporting documents associated with the Specific Condition(s) you are addressing.	This could be a written report, additional lab results, images, animal monitoring sheets etc. If you wish to provide any videos or other large files it is preferable to provide a link to a file sharing system (e.g. Onedrive)

Project outcomes

Animal Ethics Annual Progress Report	*This section (questions 3.1A to 3.6A) will only appear for annual reports for projects that are 'in progress' in Q2.3.*

| **3.1A Summarise the progress achieved in this reporting period (including results, where possible).** | You should explain what work was done on the project in this calendar year only (i.e. not in the project as a whole), even if the work didn't directly involve live animals. This helps the UAEC understand what is happening in the project and how it is progressing. |
| | This summary should describe which project treatment groups any animals used this year belonged to. (e.g. 5 rats were used from control group 3 in the 2 week timepoint). |

| **3.2A If relevant, describe any unanticipated animal welfare issues that occurred during this reporting period and how procedures could be modified in future to minimise adverse impacts on animals.** | NOTE: outline events that occurred this calendar year only (i.e. not in the project as a whole) |
| | You should discuss any events which impacted animal wellbeing that were not expected, or issues that you had anticipated but occurred more frequently or to a worse degree than projected. You do not need to fully detail adverse events that have already been reported, a very brief summary of the event will suffice (include the date of the event). If appropriate, explain how you have changed procedures to reduce the risk of similar incidents, and improve animal wellbeing. |

| **3.3A If relevant, describe any other issues that interfered with the progress of the project in this reporting period, and how they were managed.** | NOTE: outline events that occurred this calendar year only (i.e. not in the project as a whole) |
| | These could be delays due to equipment problems, staffing, funding, administrative issues, natural events etc. You should explain how these issues impacted or delayed the project during this reporting period and, if appropriate, how the issues were addressed. |

3.4A If relevant, describe how procedures or methods have been or could be improved in this project to reduce adverse impacts on animal wellbeing.	Consider the 3Rs (Replacement, Reduction, Refinement) in your response.
	According to the Code '*opportunities to replace the use of animals, reduce the number of animals used and the effectiveness of strategies for supporting and safeguarding animal wellbeing, must be kept under review for the lifetime of a project. The outcome of this review must be implemented in current projects*'.
	You should use annual reporting as an opportunity to review your project. Take into consideration factors such as environmental enrichment, animal preconditioning, training of personnel, surgical or experimental techniques, equipment used etc.
	Discuss any potential areas for improvement (that will not impact the existing data etc.) in your project. You should then submit a variation request and amend your project as appropriate.
	NOTE: any changes to your project must be approved by the UAEC before they are implemented.

3.5A Are you and your team working to the conditions of your approval as determined by the UAEC? • Yes • No	*If you select, "No", question 3.6A will appear.*
3.6A Please explain why you are not working to the conditions of your approval as determined by the UAEC.	Describe any area of work on the project that you think you have conducted outside the conditions of approval. Discuss why this occurred, and how it impacted the wellbeing of the animals involved. Outline if OREI or the UAEC was notified about this happening.

Animal Ethics Final Report

3.1B Summarise the progress achieved in this reporting period.	You should explain what work was done on the project in this calendar year only (i.e. not the outcomes of the project as a whole), even if the work didn't directly involve live animals. This helps the UAEC understand what happened in the project this year and how it progressed. This summary should describe which project treatment groups any animals used in this period belonged to. (e.g. 5 rats were used from control group 3 in the 2 week timepoint). It could also include an outline of any data analysis performed.
3.2B Summarise the overall outcomes achieved against each of the stated aims of the project (including results where possible).	Describe the outcomes of the project as a whole. Your application will have listed the aims of the project. You should itemise each of the aims and explain how the project met those goals, including both positive and negative outcomes. For teaching projects you could summarise how well the course was received by the students, and whether it met the learning objectives.
3.3B Describe how the outcomes achieved justified the use of animals in this project.	Consider the principles of 'reduction' and 'replacement' in your response. Explain why the use of animals was necessary in your project. You may like to address the following:

- Did the results you achieved warrant the use of animals?
- Was the chosen animal model suitable for the project given the outcomes?
- Are there ways you could have reduced variables or bias in the project?
- Is there any way similar results could be achieved, or even part of the project could be conducted in future without using animals or using fewer animals?

You could also outline how likely it is the project results will translate to outcomes in the target species.

3.4B Did the total number of animals used in the entire project vary from the total number approved by the UAEC for the whole project? • Yes • No	*If you select, "Yes", question 3.5B will appear.* You should also select 'yes' if the numbers of animals used varied from that approved for different experimental groups in the project.
3.5B Please explain:	Consider the principles of 'reduction' in your response. What was the total number of animals used in the project compared to the groups approved in the experimental/teaching design (question 4.4) in the application? You should list the number of animals approved in each animal group as outlined your application, and then how many animals were used from each group (i.e. for the total project, not just this calendar year). Explain why any major differences occurred and what effect (if any) it had on the project outcomes. e.g. the results may have been statistically significant without needing to use the full cohort of animals. If appropriate, explain how the project outcomes differed from the anticipated project design, statistical calculations etc. Could this influence statistical calculations or reduce the number of animals used in future projects?
3.6B Describe any unanticipated animal welfare issues that occurred in this project.	You should discuss any events that impacted animal wellbeing that were not expected, or issues that you had anticipated but occurred more frequently or to a worse degree than projected. You do not need to fully detail adverse events that have already been reported, a very brief summary of the event will suffice (include the date of the event). Did the overall morbidity/mortality rate for the project align with what was predicted in your project application? Explain any significant differences in rate and why you think this occurred.

3.7B Outline how procedures in future projects could be modified to reduce any impact on animal welfare.	Consider the principles of 'refinement' in your response. According to the Code '*the effectiveness of strategies for supporting and safeguarding animal wellbeing, must be kept under review for the lifetime of a project. The outcome of this review must be taken into account when planning future projects*'. Describe any changes to methodology you would recommend for future projects, particularly modifications that would improve the wellbeing of the animals involved. You could discuss environmental enrichment, animal preconditioning, training of personnel, surgical techniques, equipment used, methods to reduce the morbiditiy/mortality rate or reduce adverse events etc.
3.8B If relevant, describe any other issues that interfered with the progress of the project and how they were managed.	These might involve equipment, staffing, funding, administrative issues, etc. Explain how these issues delayed or interrupted the project, how they were addressed, and what (if anything) could be done to prevent similar problems in the future.
3.9B Describe any tissue, samples or data from this project that is available for sharing with other researchers.	Consider the principles of 'reduction' and 'replacement' in your response. You should explain what is available for sharing, how it is stored, where it is stored and how others can access it. For wildlife projects this should include details of tissue clips or voucher specimens (including species details and where the specimens are being held). For teaching projects this could include where any video recordings of the course will be kept or made available.
3.10B List any publications, abstracts, conference presentations, reports, and other outputs that are planned or have resulted from this project.	Describe how the results of the project are being disseminated. This might also include curriculum changes, teaching outcomes, higher degree completions, etc. For teaching projects this could include the success of the class (i.e. were the learning outcomes achieved), any feedback from the course or plans for future courses. "*Effective and transparent reporting of animal-based studies is essential to inform future scientific studies and policy. Poor reporting makes it difficult for other investigators to reproduce results and to derive the maximum scientific knowledge from studies involving animals, and risks the unnecessary use of additional animals*" (Best practice methodology in the use of animals for scientific purposes). This also includes the publishing of negative results. The 'ARRIVE Guidelines' are a useful resource for reporting on animal research.

Project Approved Animal Usage

This section will only appear for Progress and Final reports.

5.1 Download the Animal Numbers Template, complete the relevant information detailing the projects' animal usage and re-upload the completed document.

Click the link in the form to download and open the 'Animal Numbers Template'.

Fill in the project details in the header. For information on the different purposes of animal use refer to the DAF guidelines for completing the animal use statistics report.

Complete the template to indicate how many animals of each species you used for each category of procedure in the calendar year you are reporting on. Instructions are provided at the top of the template document to help you complete the template.

Save the document to your computer then upload the completed template to question 5.1 of the report sub-form.

Instructions for completing the template:
- For projects where the main application form was generated in ERM:
  - Please copy and paste the information direct from the first three columns of the table in question 5.1.1 of your approved application into the corresponding columns, then complete the additional three columns.
- For 'migrated' projects from our previous ethics system where the approved application is a word document:
  - Copy and paste the species, strain and category of procedure from question 4.2 of your approved application document, then complete the additional three columns.
- Note: for all projects ensure that all species and categories listed in your approved application are included in the template, irrespective of whether or not animals of that type were used in the calendar year.
- "New animals" - animals that were used for the first time in this project in this calendar year
- "Ongoing animals" - animals that were used in this project in previous calendar years that were still alive and being used in the project this calendar year (e.g. if 10 cattle were used during Oct 2020 to Feb 2021, 10 cattle must be reported in the 2020 report and the same 10 cattle must be reported again in the 2021 report – reflecting that the same number were used in both calendar years).
- Where a project is occurring across multiple states in Australia (e.g. wildlife studies) the numbers used should also be separated by state.

- For wildlife studies you must also report any by-catch or non-target species that inadvertently were used in your project

For information on the different categories of animal procedures refer to the <u>DAF guidelines for completing the animal use statistics report.</u> The categories are:
- Observational studies involving minor interference (O)
- Animal unconscious without recovery (UWR)
- Minor conscious intervention without anaesthesia (CWA)
- Minor operative procedures with recovery (MR)
- Surgery with recovery (SR)
- Minor physiological challenge (MinC)
- Major physiological challenge (MajC)
- Death as an endpoint (D)

Declaration	*This section appears for all reports.*
4.1 Have you disclosed all new or existing conflicts of interest relating to this project to the Office of Research Ethics & Integrity? • Yes • No	Please ensure you correctly declare any pending conflicts of interest. Go to **Conflicts of Interest** for more information.
4.2 I am the Chief Investigator, or I have approval from the Chief Investigator, to submit this report.	If you have permission from the Chief Investigator to submit the form click 'sign' and enter your name here to act as an electronic signature. Once you have signed the declaration you should select 'submit' to send the form to the animal ethics team for review. If you do not have permission to submit the form on the Chief Investigator's behalf, or you would like the Chief Investigator to review the form prior to submission, click 'request signature' and enter the Chief Investigator's name and best email contact details. The Chief Investigator should then review and sign the form prior to selecting 'submit'.