**Austin Health Animal Ethics Committee**

**Amendment Submission Guideline**

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| Amendments may be reviewed by an Executive Subcommittee of the AEC only upon justification of **urgency**. All amendments approved by an Executive on behalf of the AEC must be ratified by the full committee at the next AEC meeting.Some changes are obviously minor, whereas others are more difficult to assess and may need to be considered by the full committee. The AEC will determine if the change is significant enough to require a new application. In every case, the welfare of the animals must be the first consideration. |

**Minor Amendments:**

A minor amendment may include a change to an approved project or activity where the proposed change is **not likely** to cause harm to the animals, including pain and distress.

Examples of minor amendments / modifications include:

* Addition or removal of staff
* A small change in procedure
* A change in animal numbers or strains
* An extension of duration of the project

Although there is no limitation as to how many amendments / modifications are allowed within the approved duration of the research project, minor amendments are only allowed, generally speaking, when there is no substantial change in the overall nature or direction of the project, particularly in regard to animal welfare.

**Major Amendments:**

A major amendment may include a change to an approved project or activity where the proposed change **is likely** to cause harm to the animals, including pain and distress.

Examples of major amendments / modifications include:

* Addition of a new aim (Note: this may require submission of a new project)
* Addition of a new technique/procedure not previously approved in this protocol

**An amendment may include the following:**

1. **Extension of time:** An approved research project may be extended by up to one year. It is expected that only one extension of time would be given; however, any further requests for the extension of time may be considered upon justification.

2. **Increase in animal numbers:** The increase granted will be left to the discretion of the AEC and needs to be fully justified. An appropriate example would be equipment failure where a repeated experiment is warranted and the procedures remain exactly the same.

3. **Change to a procedure:** When there is a minor change or addition and when the same number or fewer animals will be used which will not significantly affect the welfare of the animals, it can be submitted as an amendment. However, if the new procedure has not been previously approved by the AEC in any project, then this is not an amendment and should be submitted as a new project.

4. **Change of animal species:** When an animal of similar sentience, or lesser sentience is used, and the same or fewer animals will be used, then this can be submitted as an amendment as long as the procedures remain the same. If another species is being added, with extra animals being used, then this will need to be justified as to why it should not be a new application.

5. **Change of strains within species:** This can be submitted as an amendment upon justification and is in line with the other points above.

6. **Addition/removal of personnel:** When there is a change in personnel listed on an approved project, the AEC must be notified formally using an amendment form. For addition of personnel, the request must include their relevant experience with the technique/s and type of animals used in this project, if any training is required, and who will be providing the training. For the removal of personnel, please notify the AEC using an amendment form.

**notes on the completion of this amendment**

1. Ensure you are using the most recent version of the amendment form. This can be obtained from the Office for Research (aec.ethics@austin.org.au) or on the Austin [website](http://www.austin.org.au/Animal_Ethics_Submissions/New_Applications/).
2. Insert your answer in the boxes provided below each question. When necessary, boxes will expand to accommodate the length of your answer.
3. A response is required for each question.
4. Please ensure the main application form is updated to reflect the changes requested in the amendment form.
5. If you have any queries, or would like to comment on the form, please contact the Office for Research on (03) 9496 4099 or email aec.ethics@austin.org.au

**Submission Requirements:**

Please submit electronic copies to aec.ethics@austin.org.au

* **One** fee form (if applicable)
* **One** amendment form (Word format)
* **One** amendment form signed (PDF format - this can be a signed scanned copy)
* **One** tracked copy of the main application form (with an updated version number and date)
* **One** clean copy of the main application form (with an updated version number and date)

(*Tracked documents should include all additions and changes to the text and strike through any deleted original text. Please use the ‘Track Changes’ option in Microsoft Word)*

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| It is implicit in this amendment that any items not specifically addressed in this form are covered in the original application along with any previous/subsequent amendments approved by the AEC. |

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| **Application Fee:** Amendments requesting a **PROTOCOL** change attracts an application fee.E.g. increase in animal numbers, change in strain/species or change in procedure/s.*Amendments with multiple projects on one form will* ***NOT*** *be accepted.* |