

Guidelines for amendments to approved animal ethics applications

All amendments whether they are minor or major must be approved by the ACEC **before they can commence**. The criteria guiding any proposed change is the severity of impact which should be no more than originally proposed and the experimental aim and direction is the same as originally proposed. Amendments can include an increase in animal numbers, a change to a procedure, a change in animal species or a change of strains within species, the addition of staff members or students, an extension of time and the absence or change of the principal investigator. It is the responsibility of the principal investigator and or co-investigator to seek approval from the ACEC for any amendment prior to commencement. Failure to do so will mean non-compliance with the approved protocol, which will result in a breach under the *NHMRC Australian Code of Practice for the care and use of animals for scientific purposes (CI 2.2.13)* and the *Animal Research Act (Animal Research Regulation 1995, Sect 4)*. Journals also require that any material submitted for publication must have obtained the relevant ethics approval, so it is important to realise that any non-approved variations to a protocol will render the results unpublishable.

Increase in animal numbers: Any increase in animal numbers will need to be fully justified to the ACEC.

Change to a procedure: The request for a change in procedure must include the applicant's relevant experience with the proposed techniques and the severity of impact of the proposed procedure on the animal's welfare and how that impact will be minimised. Where a change has the potential to impact significantly on the welfare of the animal and where the procedure has not been previously approved by the ACEC in any project, then the change is not considered to be an amendment and should be submitted as a new project. A change from one approved procedure to another approved procedure could be considered as an amendment.

Change of animal species: Where the project uses an animal of similar sentience or lesser sentience and the same or fewer animals will be used, provided that the procedure remains the same, then it will be considered an amendment. If another species is being added, with extra animals being used, this will need proper justification as to why it should not be considered a new project.

Addition of staff members/ students: When there is a change in staff listed on an approved project, the ACEC must be notified in writing of all personnel to be added and an Animal Research Authority application for each person completed. The request must include the relevant experience with the techniques and type of animals used in the project, if any training is required and who will give that training. Where inexperience or previous experience is absent, training in specific techniques is mandatory.

Extension of time: Normally animal research proposals are approved for a period of three years with the Animal research authority renewed annually with the submission of a progress report. Where the duration of a project is for a shorter period, provided that the procedures remain the same, an extension may be granted by the ACEC.

Absence or change in Principal Investigator: In the event of the Principal investigator being absent or on leave, the ACEC must be formally notified in writing and approve the temporary person responsible for the project, who will ensure adequate supervision of the project.