Introduction
High impact research projects are considered to be those in which animals experience a moderate or large degree of pain and/or distress.

The Animal Research Review Panel carried out a survey of Animal Ethics Committees (AECs), seeking information on their evaluation of high impact projects, especially with respect to assessing the justification for these projects. The aim of this was to identify ideas and resources that may assist AECs in assessing high impact projects.

The following were issues identified by AEC members as being of particular importance:

- High impact projects are the most challenging to deal with.
- Equal consideration should be given to all species of animals used.
- The number of animals as well as the impact on individuals needs consideration.
- Access to additional information on the science and justification for proposed research, the availability of refinements including appropriate analgesia, and the availability of alternatives to animals are important.
- The routine provision to the AEC of peer review reports, where these are available, would be of assistance.
- The importance of experimental design in ensuring the most efficient use of animals and optimum derivation of useable data, and the availability of a statistician or biometrician to assist the AEC in evaluating this.
- The use of specialists to assist AECs to assess opportunities for replacement.
- More detail and discussion around the likelihood of transfer of results from animals to humans (translational research).
- The use of risk assessments in assessing projects for the likelihood of adverse outcomes.
- More extensive use of the expertise of AEC members to review projects prior to consideration at AEC meetings.
- More attention being given to investigating the likelihood of the research being successful, the expected outcomes and value of the work.

Recommendations
These recommendations should be read in conjunction with the requirements of the Australian code for the care and use of animals for scientific purposes. As stated in the Code it “provides an ethical framework and governing principles to guide decisions and actions of all those involved in the care and use of animals for scientific purposes.”

1. AECs should ensure that in considering projects, discussions routinely include the expected outcomes and overall value of the work in contributing substantially to the advancement of knowledge or the likelihood of research results being translated into practical benefits for humans or animals. The points discussed and conclusions of the AEC should be noted in the minutes in support of the AEC’s decision. (Australian Code clauses 1.6 and 1.7)
2. Establishments should consider appointing a member to the AEC, or providing access to a consultant, with specific knowledge of alternatives to animal research who can advise the AEC and researchers on possible replacements.

3. Establishments should ensure that AEC members have unrestricted access to library and electronic resources to assist them as needed to obtain background information additional to that provided in research applications. This is particularly important where AECs are seeking information on the availability of refinements including appropriate analgesia and the availability of alternatives to animals.

4. Establishments should ensure that the services of a biometrician are routinely available, either as a member of the AEC or as a consultant, to advise the AEC and researchers on experimental design and assess the likelihood of a successful outcome.

5. AECs should consider assigning members to comprehensively assess projects submitted to the AEC prior to them being discussed at a meeting, and to lead the discussions on their assigned projects.

6. Members of the AEC acting as assessors of projects should be able to liaise freely with the principal investigator, the AEC Chair and the AEC Executive Officer and have unrestricted access to any additional information necessary in completing their assessment.

7. Where peer review reports are available as part of grant applications, these should routinely be provided for the information of the AEC.

8. AECs should routinely invite principal investigators to attend committee meetings when their projects are listed for consideration, to respond directly to questions either in person or via telephone or video conference.

9. Researchers and AECs should consider the use of risk assessment tools in examining projects for the likelihood of adverse events and implementing strategies to reduce the risk and mitigate the impacts on the animals.

10. Researchers should provide AECs with a detailed assessment of alternatives that have been examined in developing their projects and comprehensive justification for why the use of animals is unavoidable and necessary.

Additional Reading


Acknowledgments

This guideline was formulated from the advice and ideas of Animal Ethics Committee members whose contributions are gratefully acknowledged. Dr Denise Sheekey is thanked for carrying out a literature review. Dr Peter Johnson is thanked for conducting a survey and drafting a guideline document.