

The University of Newcastle Animal Care and Ethics Committee

Methodology Document

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1. Context/Overview

The purpose of this document is to provide guidance to University of Newcastle (UoN) investigators working with animals about the expectations and requirements of the regulatory framework and the UoN Animal Care and Ethics Committee where projects involve collaboration between investigators at more than one institution. These guidelines cover collaboration between UoN investigators and other investigators within New South Wales, within other states and territories within Australia and within overseas institutions.

The Australian code for the care and use of animals for scientific purposes (Australian Code) Section 2.6.8 states:

'Investigators must notify the AEC in writing if they are involved in collaborative studies using animals at another institution, or if they are named in an application to the AEC of another institution.'

The Australian Code further requires that *'Institutions must ensure that projects involving investigators from more than one institution, or the care and use of animals at more than one institution, are approved and monitored by the responsible AECs'*. (Section 2.6.4)

Other relevant extracts of the Australian Code appear in Appendix II.

For information about animal research carried out on non UoN land, where there is no collaboration with investigators from other institutions see ACEC document 38: 'Animal research conducted on non university land'.

2. Definitions

In the context of this document:

AEC means Animal Ethics Committee and has the same meaning as Animal Care and Ethics Committee at the University of Newcastle;

employing institution means the institution employing the staff investigators and enrolling the student investigators;

host institution means the institution at which the animal research is being carried out;

investigator means researcher or teacher using animals and includes student investigators.

3. Guidelines

Staff and students associated with the University of Newcastle may be involved with collaborative animal research in the following situations:

- a) Conducted solely within institutions other than the University of Newcastle.
- b) Conducted solely at the University of Newcastle, but involving researchers from other institutions.
- c) Conducted partly on premises/locations associated with the University of Newcastle, and partly on premises/locations not associated with the University where either;
 - (i) animals are transferred between institutions as part of the project, or
 - (ii) animals remain within their respective institutions and specific parts of the project are carried out entirely at each institution.

A summary of the requirements for each type of collaboration can be found in appendix I.

Researchers are encouraged to contact the University of Newcastle Animal Ethics Officer well in advance of commencement of the collaborative research so that communication between the relevant ACECs can be established where required. This may also act to facilitate and streamline the process of ACEC approval.

If relevant, the University of Newcastle will develop a formal agreement with the other institution/s regarding the approval, conduct and monitoring of the research. This agreement may delegate the approval of the project to one institutional ACEC. In some cases, there may be prior agreement between the University of Newcastle and the other institution/s regarding acceptance by all relevant ACECs of a single application form to facilitate submission of an application to each relevant ACEC.

Formal agreements between collaborating institutions are necessary to ensure that the host institution reports any breaches to the employing institution and that the employing institution accepts responsibility for taking appropriate action against its employees and students where they contravene the legislation.

Note: Where investigators will not be handling live animals or directing activities involving live animals, there is no need for ACEC approval. This applies whether UoN researchers are visiting other institutions or external personnel are visiting UoN. However it is still necessary to adhere to any local legislation, regulation or codes.

3.1 Research conducted SOLELY within institutions other than the University of Newcastle

The actions required of a UoN investigator working with research animals solely within another institution will depend on whether that institution is within Australia and thus subject to the NSW Australian Code, and NSW Animal Research Act and Regulations or state/ territory legislation; or overseas.

Where an employee or student of one institution proposes to carry out animal research at another institution, the ACEC of the "host" institution would have a supervisory role over the research, but the employing institution would continue to have authority over the employee/ students actions and would be responsible, in terms of vicarious liability, for any acts of its employee/ student which contravene the Animal Research Act, or other relevant legislation.

3.1.1 Institutions within Australia.

In this case, the investigator must:

- Ensure that they obtain approval from the collaborating institution's AEC for their addition to the project.
- Notify the University of Newcastle ACEC in writing that the research is being conducted, the site of the research, the institutional Animal Ethics Committee (AEC) that has approved the research, and the AEC approval number covering the research.

3.1.2 Institutions overseas.

In this case, the researcher must:

- Notify the University of Newcastle ACEC in writing that the research is being conducted, the site of the research, and the institutional AEC that has approved the research.
- Where available in English, provide a copy of the application submitted to that institutional AEC and the notification of approval granted by that AEC to the UoN ACEC.
- Complete a UoN ACEC application with reference to the supervising institution's application where information is already provided in that application.
- In countries without an animal ethics approval process equivalent to that required by the Australian Code, include in the application to the UoN ACEC, information on compliance with local legislation, regulations and codes and whether such compliance creates inconsistencies with the guiding principles of the Australian Code.

3.2 Conducted solely at the University of Newcastle, but involving researchers from other institutions

Whether the collaboration is with an institution within NSW, within Australia or overseas, the investigator must:

- Submit an application to the UoN ACEC clearly describing the collaboration within that application. Where external personnel are being added to an existing ACEC approved protocol, this may be by way of a variation application.

- Include the collaborators names and experience in the techniques to be carried out, in the ACEC application.

3.3 Research conducted partly on premises/locations associated with the University, and partly on premises/locations not associated with the University.

3.3.1 Live animals are transferred between institutions (in Australia or overseas).

In this case, approval will be required from both the University of Newcastle ACEC and the AEC of all other institutions involved. The investigator must:

- Submit an application to the University of Newcastle ACEC, identifying the collaboration in relevant sections of the application form. The research project must be described in full in the application, and the sites for the conduct of all aspects of the project clearly identified. Details of the transport of the animals must be included in the application.
- Obtain approval from the AEC of the other relevant institution/s.
- Provide the University of Newcastle ACEC with a copy of the application submitted to the AEC of the other institution/s, and the notification of approval granted by that AEC.
- Ensure all necessary documentation is completed and permits obtained, where required by external bodies e.g. Materials Transfer Agreement (MTA), Genetically Modified Organism (GMO) licence, Environment and Heritage (OEH) licence etc.

3.3.2 Animals remain within their respective institutions and specific parts of the project are carried out entirely at each institution

In this case, approval will be required from both the University of Newcastle ACEC and the AEC of all other institutions involved. The researcher must:

- Submit an application to the University of Newcastle ACEC, identifying the collaboration in relevant sections of the application form.
- The research project must be described in full in the application, and the sites for the conduct of all aspects of the project clearly identified, however detail of procedures and animal numbers is only required for those animals being used at UoN.

4. Essential Supporting Documents

- 4.1.1.** Australian code for the care and use of animals for scientific purposes.
- 4.1.2.** Animal Research Policy.
- 4.1.3.** Animal Care and Ethics Committee Procedure.
- 4.1.4.** Animal Care and Ethics Committee Guideline.

5. Related Documents

5.1.1. ACEC 38; Animal Research Conducted on non university land.

Appendix I

Type of Collaboration	Location of Collaborating Institution	Investigator's Responsibility	Animal Ethics Officer Responsibility
<p>Research conducted SOLELY within institutions other than the University of Newcastle, where UoN researchers are involved in live animal procedures.</p>	<p>NSW, or other State or Territory within Australia.</p>	<p>UoN ACEC approval NOT REQUIRED- but notification to UoN ACEC is required.</p> <ol style="list-style-type: none"> 1. Gain approval from collaborating institution AEC for project in which UoN researchers are named. 2. Notify the University of Newcastle ACEC in writing that the research is being conducted, the site of the research, the institutional Animal Ethics Committee (AEC) that has approved the research, and the AEC approval number covering the research. 	<p>Set up formal agreement between collaborating institutions including:</p> <ol style="list-style-type: none"> 1. How the host institution reports any breaches to the UoN 2. That UoN accepts responsibility for taking appropriate action against its employee/students where they contravene the legislation
	<p>Overseas</p>	<p>UoN ACEC approval IS REQUIRED:</p> <ol style="list-style-type: none"> 1. Gain approval from the collaborating institution's AEC equivalent (naming the UoN researchers involved in the project). 2. Complete a UoN ACEC application with reference to the supervising institution's application where information is already provided in that application. 3. Provide a copy of the application submitted 	<p>Set up formal agreement between collaborating institutions including:</p> <ol style="list-style-type: none"> 1. How the host institution reports any breaches to the UoN 2. That UoN accepts responsibility taking appropriate action against its employee/ students where they contravene the legislation. 3. Details of monitoring and

		<p>to that institutional AEC and the notification of approval granted by that ACEC to the UoN ACEC (where available in English).</p> <p>4. In countries without an animal ethics approval process equivalent to that within NSW, include in the application to the UoN ACEC, information on compliance with local legislation, regulations and codes and whether such compliance creates inconsistencies with the guiding principles of the Australian Code.</p>	inspection requirements.
<p>Conducted SOLEY at the University of Newcastle, but involving researchers from other institutions.</p>	NSW, other states and territories within Australia, overseas institutions	<p>UoN ACEC approval IS REQUIRED:</p> <ol style="list-style-type: none"> 1. Submit an application (which may be a variation application) to the UoN ACEC clearly describing the collaboration within that application. 2. Include the collaborators names and experience in the techniques to be carried out, in the ACEC application. 	<p>Set up formal agreement between collaborating institutions including:</p> <ol style="list-style-type: none"> 1. How the UoN reports any breaches to the employing institution 2. That the employing institution accepts responsibility for taking appropriate action against its employee/ students where they contravene the legislation.
<p>Research conducted PARTLY on premises/locations associated with the University, and partly on premises/locations not associated with the University:</p> <p><u>Live animals are transferred between</u></p>		<p>UoN ACEC approval IS REQUIRED:</p> <ol style="list-style-type: none"> 1. Submit an application to the University of Newcastle ACEC, identifying the collaboration in relevant sections of the application form. The research project must be described in full in the application, and the sites for the conduct of all aspects of the project clearly identified. 2. Obtain approval from the AEC of the other 	<p>Set up formal agreement between collaborating institutions including:</p> <ol style="list-style-type: none"> 1. Details of monitoring and inspection requirements- generally each AEC will monitor and inspect that part of the project that occurs at its institution.

<p><u>institutions</u></p>		<p>relevant institution/s.</p> <ol style="list-style-type: none"> 3. Provide the University of Newcastle ACEC with a copy of the application submitted to the AEC of the other institution/s, and the notification of approval granted by that AEC. 4. Where the majority of the project occurs at the collaborators institution, the ACEC will accept a copy of the application to the collaborating institution plus an application to the UoN ACEC that references the collaborators AEC application and only completes in detail the procedures that will take place at UoN. 5. Ensure that Attachment K- transport of animals is attached to the UoN application. 6. Ensure all necessary documentation is completed and permits obtained, where required by external bodies e.g. Materials Transfer Agreement (MTA), Genetically Modified Organism (GMO) licence, Environment and Heritage (OEH) licence etc. 	
<p>Research conducted partly on premises/locations associated with the University, and partly on premises/locations not associated with the University:</p> <p><u>Animals remain within their respective</u></p>	<p>NSW, other states and territories within Australia, overseas institutions.</p>	<p>UoN ACEC approval IS REQUIRED:</p> <ol style="list-style-type: none"> 1. Submit an application to the University of Newcastle ACEC, identifying the collaboration in relevant sections of the application form. 2. The research project must be described in full in the application, and the sites for the conduct of all aspects of the project clearly 	<p>Set up formal agreement between collaborating institutions including:</p> <ol style="list-style-type: none"> 1. Details of monitoring and inspection requirements- generally each AEC will monitor and inspect that part of the project that occurs at its institution.

<u>institutions and specific parts of the project are carried out entirely at each institution</u>		identified, however detail of procedures and animal numbers is only required for those animals being used at UoN.	
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Appendix II

Relevant Extracts of the Australian Code:

Projects involving more than one institution and/or animal ethics committee

Responsibilities of institutions and animal ethics committees

2.6.4 Institutions must ensure that projects involving investigators from more than one institution, or the care and use of animals at more than one institution, are approved and monitored by the responsible AECs. Procedures must be developed and implemented to ensure that:

- (i) all parties involved are aware of, and can meet, their respective responsibilities under the requirements of the Code
- (ii) a project does not commence before each AEC approves, or the delegate AEC approves (see Clause 2.6.5), activities to be conducted by members of its institution. Each AEC should be responsible for approval and monitoring of animal care and use that occurs at the institution for which it acts
- (iii) the responsible AECs are aware of all aspects of the proposed use of animals, and consider the cumulative effects on the wellbeing of the animals involved
- (iv) the responsible AECs can inspect the animals so that all phases of the project are monitored, including any animal transport between sites
- (v) animals will receive appropriate care in all phases of the project, including any animal transport between sites
- (vi) clear communication channels are established between all AECs and all investigators

2.6.5 Institutions may agree to one AEC (the delegate AEC) approving the entire project, provided that all institutions involved agree to delegate the responsibility for decision making to, and support the necessary actions of, that AEC.

2.6.6 Arrangements between institutions should be as a formal agreement. Institutions should avoid unnecessary duplication of processes.

2.6.7 Arrangements should include mechanisms for reporting non-compliant activities between institutions and AECs.

Responsibilities of investigators

2.6.8 Investigators must notify the AEC in writing if they are involved in collaborative studies using animals at another institution, or if they are named in an application to the AEC of another institution (see Clause 2.4.9).

Projects conducted by Australian investigators and institutions in other countries

Responsibilities of institutions

2.6.9 Institutions should have procedures in place to ensure that, as a minimum, projects conducted on behalf of the institution in other countries:

- (i) comply with the governing principles of the Code, provided that such compliance does not breach relevant local legislation
- (ii) are not conducted in other countries as a mechanism of avoiding compliance with the Code.

2.6.10 Institutions that operate facilities that use animals for scientific purposes in other countries should ensure that projects conducted at those facilities comply with the principles of the Code as a minimum, provided that such compliance does not breach relevant local legislation.

Responsibilities of animal ethics committees

2.6.11 When considering approval for a project to be conducted in another country, the AEC may accept approval granted by a local AEC or its equivalent in that country if it is satisfied that outcomes would be equivalent to those expected through application of the Code.

2.6.12 The AEC must ensure that animal care and use in the other country is adequately monitored. The AEC may appoint an agent or delegate to conduct the monitoring and inspection on its behalf.

Responsibilities of investigators

2.6.13 Investigators responsible for a project conducted in another country should, as a minimum, ensure that:

- (i) the project complies with the governing principles of the Code, provided that such compliance does not breach relevant local legislation
- (ii) the project is not conducted in another country as a mechanism of avoiding compliance with the Code.

2.6.14 Investigators who plan to use animals in another country must obtain approval from their institutional AEC for such use. Investigators must provide the AEC with advice on how the proposed project can meet the principles of the Code, taking into account compliance with local requirements.