

UTS ANIMAL CARE AND ETHICS COMMITTEE (ACEC)

TERMS OF REFERENCE

Preamble

As an institution involved in the care and use of animals for scientific purposes, the University of Technology, Sydney (UTS) has established an Animal Care and Ethics Committee (ACEC) in accordance with the [Australian Code for the Care and Use of Animals for Scientific Purposes 8th Edition 2013](#) (the Code) and the NSW Animal Research Act.

The UTS ACEC is a Vice-Chancellor's committee reporting through the Deputy Vice-Chancellor (Research) (DVCR).

These Terms of Reference:

- Aim to describe the purpose, scope and structure of the ACEC, and outline roles, responsibilities and procedures.
- Have been developed in accordance with the Code (clause 2.2.18) and therefore include provision for
 - The scope of the ACEC's responsibilities for ethical review, approval and monitoring of animal care and use
 - The ACEC's institutional accountability
 - The ACEC's mechanisms of reporting
 - The way in which the ACEC meets the requirements for categories of minimum membership.
- Come into effect upon approval by the ACEC
- Are to be reviewed at least every three years from the date of approval
- Are to be publicly available.

Throughout this document:

- References to the Code are cited in brackets and relate to the relevant section and clause.
- The term 'research' also refers to teaching and other activities involving animals as defined in the Code where applicable.
- The term 'project' may refer to any activity in which animals are used in research or teaching as defined by the Code and relevant legislation.

Feedback on these Terms of Reference is welcome and will be considered by the ACEC as appropriate.

Scope of the ACEC's responsibilities (2.2.18[i])

Primary responsibility of the ACEC

The primary responsibility of the ACEC is to ensure, on behalf of UTS, that all activities relating to the care and use of animals are conducted in compliance with the Code (2.3.1), the *NSW Animal Research Act 1985* and the *Animal Research Regulation 2010*.

Ethical review and approval (Code 2.2.18[i])

The ACEC's responsibilities for ethical review and approval of animal care and use are to:

- Review applications for projects and approve only those that are ethically acceptable and conform to the requirements of the Code (2.3.2[i]). Consideration of what is deemed to be ethically acceptable shall be guided by the ethical framework contained in all clauses of Section 1 of the Code; these processes must therefore require that:
 - Respect for animals must underpin all decisions
 - Methods ('alternatives') that replace or partially replace the use of animals must be investigated, considered and, where applicable, implemented
 - Ethical review must balance whether the potential effects on the wellbeing of the animals involved is justified by the potential benefits;
- Review applications for activities associated with the care and management of animals in facilities, including procedures applicable to breeding programs integral to the maintenance of an animal line, and approve only those activities that are ethically acceptable and conform to the requirements of the Code (2.3.2[ii]);
- Conduct follow-up review of approved projects when scheduled (at least annually) and when circumstances trigger additional follow-up review, including: (a) proposed amendment to an approved project (b) review of annual progress of an ongoing project or activity (c) unexpected adverse events and allow the continuation of approval for only those projects and activities that are ethically acceptable and conform to the requirements of the Code (2.3.2[iii], 2.2.32 [iii]);
- Monitor the care and use of animals, including housing conditions, practices and procedures involved in the care of animals in facilities (2.3.2[iv]). This shall include the acquisition, transportation, breeding, housing, care, practices and procedures in projects approved by the ACEC;
- Take appropriate actions regarding unexpected adverse events (2.3.2[v]). Actions must be directed towards ensuring that animal wellbeing is not compromised, the issue is addressed promptly, and activities that have the potential to adversely affect animal wellbeing cease immediately. Actions may also include consulting with relevant people and, where necessary, suspending or withdrawing approval for the project or activity (2.3.24);
- Take appropriate actions regarding non-compliance (2.3.2[vi]). Actions must be directed towards ensuring that animal wellbeing is not compromised, the issue is addressed promptly, and activities that have the potential to adversely affect animal wellbeing cease immediately. Actions may include suspending or withdrawing approval for the project. Actions must be taken to address the issues in consultation with the person(s) involved and when considered

necessary, such matters are referred to the UTS management for action and appropriate follow-up (2.3.25);

- Approve guidelines for the care and use of animals on behalf of UTS (2.3.2[vii]) and provide advice and recommendations to UTS (2.3.2[viii]). This may be through the Deputy Vice-Chancellor (Research) or other appropriate channels and should include advice on measures considered necessary to ensure that the standards of the Code are met;
- Report on its operations to UTS (2.3.2[ix]). This shall include a report detailing the activities of the ACEC to the Vice-Chancellor at least annually;

In fulfilling its responsibilities for ethical review and approval, the ACEC shall:

- Provide competent, fair, consistent and timely review of applications and reports related to the care and use of animals (2.3.3);
- Make a judgment on whether the proposed or continued use of animals is ethically acceptable. This judgment must:
 - Be based on information provided by the applicant that demonstrates the application of the Code's Governing Principles; and
 - Balance whether the potential effects on the wellbeing of the animals involved is justified by the potential benefits (2.3.4);
- Approve only those projects that are ethically acceptable and conform to the requirements of the Code (2.3.5);
- Only consider and approve applications for new projects and activities, and the ongoing approval for existing projects and activities, at quorate meetings of the ACEC;
- Follow procedures which describe how applications and reports will be assessed in a manner that is fair to applicants and acceptable to all members, including the need to provide ACEC members with information in a timely manner (2.3.7);
- Base its decisions on the information it receives from the applicant's documentation and in any direct discussions with the applicant, and may use information in addition to that obtained from the applicant (2.3.8);
- Decide that:
 - An application to commence a project, or amend an approved project, is approved with or without conditions, deferred subject to modification, or not approved.
 - Following review of the annual report for an approved project and possible consultation with the applicant, the approval for the project is continued, suspended, modified or discontinued
 - An approval is suspended or withdrawn (2.3.9);
- Base its decisions on a thorough, fair and inclusive process of discussion and deliberation by ACEC members, and decisions should be made only by those able to participate throughout the discussion (2.3.10);

- Make decisions on the basis of consensus. Where consensus cannot be reached after reasonable effort to resolve differences, the ACEC should explore with the applicant(s) ways of modifying the project that may lead to consensus. If consensus is still not achieved, the AEC should only proceed to a majority decision (which may be a vote either by show of hands or a written vote) after members have been allowed a period of time to review their positions, followed by further discussion (2.3.11). Every effort should be made to obtain agreement from one member of each category. A dissenting member may request that his/her view be formally recorded in the Minutes.
- Ensure that members with a conflict of interest will withdraw from the meeting during decision making. Once such members have withdrawn, the remaining members must constitute a quorum as defined by in Clause 2.2.25 of the Code—that is, one member from each of the membership categories A, B, C and D, with Categories C and D together representing at least one-third of members present (2.3.12);
- Make decisions as promptly as possible (2.3.13);
- When pilot studies are proposed, regard these as integral to the overall project, especially to enable assessment of the feasibility of the project and the potential for refinement and reduction. They will be assessed by the ACEC according to the criteria applied to project approval (2.3.14);
- When considering approval for the reuse of animals, take into account:
 - The pain and distress, and any potential long-term or cumulative effects, caused by previous activities and conditions
 - The time allowed for recovery of the animals between activities
 - Whether an animal has fully recovered from the previous activities
 - The pain and distress likely to be caused by the next and subsequent activities
 - The total time over which an animal will be used (2.3.15);
- In determining the duration of approval for individual projects, take into account the number of years for which the project is funded, any milestones or stages outlined in the project, and any formal agreements between the institution and funding bodies (2.3.16);
- Investigators may appeal a decision made by the ACEC. Where complaints concerning the process of review of an application or report cannot be resolved by communication between the complainant and the ACEC, the complaint should be referred to the DVCR for review of the process followed by the ACEC. Following this review, the ACEC may need to review its process in reaching its decision regarding the application or report, and re-evaluate its decision in light of the reviewed process. The ultimate decision regarding the ethical acceptability of an activity lies with the ACEC and must not be overridden (5.6).

Monitoring the care and use of animals

- The ACEC will monitor the care and use of animals by inspecting animals, animal housing and the conduct of procedures, and/or reviewing records and reports (2.3.17).
- The ACEC must monitor all activities relating to the care and use of animals (including the acquisition, transport, breeding, housing and husbandry of animals) on a regular and ongoing basis to assess compliance with the Code and decisions of the ACEC. The ACEC must

ensure that identified problems and issues receive appropriate follow-up and, if necessary, refer suspected breaches of the Code to the Manager, Research Integrity and Research Programs, Office of the DVCR (2.3.18).

- The ACEC should monitor activities that are likely to cause pain or distress at an early phase during the conduct of the activity. This requirement should be a condition of approval for the project or activity (2.3.19).
- A Category C or D member of the ACEC should participate in animal facility inspections (2.3.20).
- The ACEC should determine the frequency and timing of inspections although an inspection of each facility operated by UTS should take place at least once a year. Influencing factors include the number and accessibility of sites, the number and types of projects and activities, and whether inspections can be combined with scheduled ACEC meetings. In addition, the ACEC may decide that certain projects or activities require more frequent inspection than others. Inspections may be announced or unannounced (2.3.21).
- The ACEC must maintain records of inspections that include the names of attendees, observations, any identified problems, recommended actions, ongoing or outstanding issues, and outcomes (2.2.30, 2.3.22).
- The ACEC may delegate authority to suitably qualified people to monitor and inspect animal care and use at sites that are remote or where access is difficult. The ACEC should indicate the aspects to be reported on, steps to be taken to avoid conflict of interest and any ancillary evidence desired such as still images or video (2.3.23).
- The findings of inspections should be reported to the DVCR; this reporting may be as a part of minutes of ACEC meetings, part of an annual report or reported separately. If findings are considered to be of a serious nature, the DVCR should be notified as soon as practicable.

Unexpected adverse events

- The Code defines an Unexpected Adverse Event as “an event that may have a negative impact on the wellbeing of animals and was not foreshadowed in the approved project or activity.” Examples include but are not limited to:
 - Death of an animal or group of animals
 - Adverse effects on animal welfare following a procedure or treatment that were not expected
 - Adverse effects in a larger number of animals than predicted during the planning of the project
 - A greater level of pain or distress than was predicted
 - Power failures, inclement weather, emergency situations or other factors external to the project that have a negative impact on the welfare of the animals (the Code’s ‘Definitions’).
- The ACEC will take appropriate action in response to unexpected adverse events to ensure that animal wellbeing is not compromised, the issue is addressed promptly, and activities that have the potential to adversely affect animal wellbeing cease immediately. Actions may include

consulting with relevant people and, where necessary, suspending or withdrawing approval for the project (2.3.24).

- In situations where an Unexpected Adverse Event requires urgent action to minimise adverse effects on animal wellbeing, responsibility for ensuring an appropriate response will be delegated automatically to the Animal Facility Manager, the consultant veterinarian, the ACEC Chair, or a Category A (veterinarian) member of the Committee until such time as the matter can be considered by the full Committee. Before proceeding with treatment or euthanasia of an animal in such cases, reasonable steps must be taken to consult with the responsible investigator unless this would unduly prolong an animal's pain or distress. All such cases must be reported promptly to the responsible investigator and the ACEC, with reasons given for the action taken, and details confirmed in writing. The matter must be considered by the full Committee as soon as reasonably practicable.

Approval of guidelines (2.1.5 [iv - vi])

UTS must develop, implement and promote guidelines to promote compliance with the Code. These guidelines must be developed in consultation with and must be approved by the ACEC.

Guidelines must cover:

- Assessment and ensuring the competence of people involved in the care and use of animals;
- Strategies to ensure the maintenance of a health status of the animals that safeguards animal wellbeing and meets the requirements of their proposed use
- Monitoring and assessment of animals to ensure that any harm, including pain and distress, is promptly detected and managed
- Actions required for unexpected adverse events and emergencies including those that require welfare interventions such as the emergency treatment or humane killing of any animal, to ensure that adverse impacts on animal wellbeing are addressed rapidly. Such guidance should include timeframes for actions, prompt reporting to the AEC, liaison between animal carers and investigators, and circumstances when consultation with a veterinarian, the performance of a necropsy by a competent person, and access to diagnostic investigations are required;
- Approval, in advance, for the immediate use of animals, if required, for the diagnosis of unexplained and severe disease outbreaks, or morbidity/mortality, in animals or people
- Ensuring availability and access to veterinary advice for the management and oversight of a program of veterinary care, quality management and project design to safeguard animal wellbeing.
- Procedures for students wishing to express conscientious objection to the use of animals in the case of teaching activities.

Approval of Standard Operating Procedures (2.2.33 – 2.2.36)

- UTS may develop Standard Operating Procedures (SOPs) relating to the care and use of animals.
- Any such SOPs must be developed in consultation with and approved by the ACEC.

- SOPs must not lessen the rigor applied by the ACEC when evaluating procedures involving the care and use of animals.
- The ACEC may only accept an SOP within an application under the following conditions:
 - The SOP must have current approval from the ACEC (i.e. approved within the last three years or as otherwise determined by the ACEC).
 - The SOP must include the date of approval or last review by the ACEC
 - Investigators named in the application must be competent to implement the SOP
 - Any variation to an SOP must be described in the application and should be considered as a prompt for review of the SOP.
- The ACEC must review SOPs within three years of approval. SOPs which have not been reviewed by the ACEC for three years or more will lapse.
- Approved SOPs must be made available to all relevant people, including ACEC members.

Provide advice and recommendations to the institution

The ACEC must provide advice and recommendations to the institution regarding the care and use of animals for scientific purposes conducted on behalf of the institution, and strategies required ensuring that the requirements of the Code are maintained and that matters affecting animal wellbeing are addressed (2.3.27).

The ACEC must be consulted during the planning of new facilities or refurbishment or modification of existing facilities for the care and use of animals used for scientific purposes. New, refurbished or modified facilities must be inspected and approved for use by the ACEC prior to housing animals to establish that the facility meets the Code's requirements for animal housing (2.1.6[v], 3.2.14, 3.2.17-20) and environmental conditions (3.2.17[i]).

Institutional accountability (Code 2.2.18[ii])

Governance

For the purpose of these Terms of Reference:

- The Governing body (as defined by the Code) shall be the UTS Council.
- The Deputy Vice-Chancellor (Research) representing the Vice-Chancellor shall be the person responsible for overall institutional governance with respect to the care and use of animals. This includes providing adequate resources to ensure that the ACEC and people involved in the care and use of animals can meet their responsibilities, including monitoring animals and managing adverse impacts on their wellbeing (2.1.5[i]).

Membership (Code 2.2.18 [iv])

Membership of the ACEC must allow the Committee to meet its responsibilities. Membership must comprise at least four people, one from each of four categories of membership as set out below (2.2.1)

Chair and Deputy Chair

A chairperson of the ACEC must be appointed (the Chair).

The Chair should either hold or have previously held a senior position in the institution or may be external and should be a person who is independent of the care and use of animals for scientific purposes. The Chair may be appointed in addition to Category A to D members (2.2.2, 2.2.3).

The Chair should be nominated by the DVCR.

Appointment of the Chair must be approved by the NSW Animal Research Review Panel.

The Chair must be provided with the necessary support and authority to carry out the role.

The ACEC may appoint a Deputy Chair to act in the absence of the Chair.

The positions of Chair and Deputy Chair will initially be for one year, with extension to three years as deemed appropriate by the DVCR. The Chair and Deputy Chair will normally serve for a total of one term of three years in duration. Where deemed appropriate by the DVCR, these positions may be extended for a period of up to three years.

Members

Membership of the ACEC shall comprise of at least one person from each of four categories of membership (2.2.4):

- Category A—a person with qualifications in veterinary science that are recognised for registration as a veterinary surgeon in Australia, and with experience relevant to the institution's activities or the ability to acquire relevant knowledge.
- Category B—a suitably qualified person with substantial and recent experience in the use of animals for scientific purposes relevant to the institution and the business of the ACEC. This must include possession of a higher degree in research or equivalent experience. If the business of the ACEC relates to the use of animals for teaching only, a teacher with substantial and recent experience may be appointed. Any UTS staff member who engages in animal research and who meets the criteria for Category B membership must be prepared to serve one or more terms on the ACEC as a Category B member.
- Category C—a person with demonstrable commitment to, and established experience in, furthering the welfare of animals, who is not employed by or otherwise associated with the institution, and who is not currently involved in the care and use of animals for scientific purposes. Veterinarians with specific animal welfare interest and experience may meet the requirements of this category. While not representing an animal welfare organisation, the person should, where possible, be selected on the basis of active membership of, and endorsement by, such an organisation.
- Category D—a person not employed by or otherwise associated with the institution and who has never been involved in the use of animals in scientific or teaching activities, either in their employment or beyond their undergraduate education. Category D members should be viewed by the wider community as bringing a completely independent view to the ACEC, and must not fit the requirements of any other category.

Additional appointments to assist the ACEC

Up to three UTS staff members representing the Ethics Secretariat may attend meetings of the ACEC. These representatives will not be members of ACEC but may provide advice and administrative support.

A person responsible for the routine care of animals within the institution shall be appointed to the ACEC (2.2.5). This may be a member of technical staff (manager and/or deputy manager) from a UTS animal facility who will be in attendance to advise on relevant issues, such as capacity, animal husbandry etc. This representative will not be a member of ACEC but will serve in an advisory capacity.

Additional members with skills and background of value to the ACEC may be appointed to the Committee (2.2.6). This may include a representative of the Animal Users' Group to advise on matters relevant to the Committee's deliberations. This representative may serve concurrently as a Category B member of the ACEC.

The ACEC may invite people with specific expertise to provide advice, as required (2.2.7).

Balance of membership

Categories C and D must together represent at least one-third of the ACEC membership (2.2.8).

Appointment, reappointment and retirement of members

The UTS Ethics Secretariat under the supervision of the Research Ethics Manager shall develop procedures for the appointment, reappointment and retirement of ACEC members (2.2.9).

The Research Ethics Manager and the Chair will monitor the ACEC membership need in accordance to the Code.

Before appointment, all members of the ACEC must acknowledge in writing their acceptance of the terms of reference of the ACEC and any requirements for confidentiality required by the institution (2.2.11).

The Research Ethics Manager should ensure that ACEC members undergo appropriate induction and training in using the Research Master Online system for review of ethics applications, and have access to appropriate education programs and resources (2.2.12).

The membership of the Committee shall be approved by the NSW Animal Research Review Panel (ARRP) and the DVCR of UTS.

The term of membership will normally be for three years from the date of appointment. A member can be re-appointed for an additional period as required.

Members may resign from the ACEC at any time by advising the ACEC Chair in writing with a minimum two month notification period. The Chair will advise the DVCR of the resignation.

The DVCR may, after consultation with the ACEC Chair retire a member of the ACEC from the Committee.

Responsibilities of the Chair

The Chair is responsible for impartially guiding the operation of the ACEC, advising the DVCR the levels of resources required by the Committee, resolving conflicts of interest related to the business of the ACEC, and representing the ACEC in any negotiations with the institution's management (2.2.13).

Responsibilities of members

Each member is responsible for deciding whether, in their own judgment, an application or other matter under consideration by the ACEC is ethically acceptable (see Clause 1.3) and meets the requirements of the Code (2.2.14). A judgment as to whether a proposed use of animals is ethically acceptable must be based on information that demonstrates the principles in Clause 1.1 of the Code (outlined at the top of this document), and must balance whether the potential effects on the wellbeing of the animals involved is justified by the potential benefits (1.3).

To fulfil this responsibility, members should:

- Be familiar with the Code and other policies and guidelines relevant to the business of the ACEC;
- Provide opinions on the ethical acceptability of applications and other matters under consideration by the ACEC (2.2.15).

Procedures must include the declaration of interests by prospective members and the management of conflicts of interest in making appointments (2.2.10).

During their appointment to the ACEC and before any deliberations of the ACEC, members and prospective members must declare any interest that could influence the objectivity of their decision making (2.2.16).

Members and others who attend meetings or who are privy to material relating to the activities of the ACEC must maintain confidentiality regarding the content of applications and the Committee's deliberations in accordance with institutional requirements (2.2.17). Content of applications or other matters subject to the ACEC's deliberations must not be discussed with anyone other than members of the Committee and the Ethics Secretariat, without the permission of the researcher.

Members are required to attend at least 80% of the meetings held during each year of their appointment and to provide written comments on the protocols being reviewed.

Members will be expected to participate in inspections of animal facilities.

If there are concerns that a member of the ACEC is failing to meet their obligations to the work of the Committee and/or its role in ensuring compliance with the Code, the matter shall be referred to the Chair and the Research Ethics Manager for consideration. If the concerns are deemed to have substance, the matter shall be raised with the member who will be given reasonable opportunity to respond. Should the matter remain unresolved, independent assistance may be sought through channels such as mediation, UTS Human Resources partners or the NSW Animal Welfare Unit. Strict confidentiality must be observed throughout all such proceedings and rights of appeal must be available.

Terms of Reference

These Terms of Reference shall:

- Come into effect upon approval by the ACEC
- Be publicly available on the UTS website 2.2.1[ii])
- Be reviewed every three years by the ACEC, or more frequently if necessary.

General administrative support

The Ethics Secretariat under the supervision of the Research Ethics Manager shall be responsible for establishing and implementing procedures for the effective membership, governance, operation and resourcing of the ACEC to enable it to meet its responsibilities under the Code, relevant institutional policies and legislation and to promote competent and timely ethical review of animal care and use (2.2.1[iii, iv]).

These procedures shall include provision of the resources required for the ACEC to carry out its responsibilities and for UTS to respond effectively to recommendations from the ACEC regarding resources and workloads. Resources should include:

- Staffing, administrative assistance, and financial resources;
- Induction, training and continuing education of ACEC members;
- The reimbursement of out-of-pocket travel expenses of ACEC members and “thank you” voucher at the end of the calendar year (2.2.19).

The Ethics Secretariat under the supervision of the Research Ethics Manager shall also establish procedures to include declaration of interests and management of conflicts of interest, confidentiality, appointment of and delegation of functions to an ACEC Executive, administrative processes, meeting procedures, communication, complaints and non-compliance, records and documentation (2.2.20):

Administrative support for the ACEC shall be provided through the ‘Ethics Secretariat under the direction of the Research Ethics Manager. Additional persons may be included in the activities of the Secretariat at the discretion of the Research Ethics Manager.

The Secretariat shall:

- Develop policies and procedures for the submission, receipt and processing of ethics applications and reports to the ACEC, and make these policies and procedures readily available (2.2.24).
- Establish, maintain communication with and respond to inquiries from the Animal Welfare Unit of NSW Department of Primary Industries, the NHMRC Animal Welfare Committee and relevant State and Territory licensing and accreditation bodies.

Declaration of interests and management of conflicts of interest

Procedures for declaration of interests and management of perceived or actual conflicts of interest involving ACEC members, and experts whose advice is sought by the ACEC, shall require people with a conflict of interest to remove themselves from the ACEC’s decision making on matters that relate to the conflict of interest (2.2.21).

All members will be asked to declare any conflict of interests at the beginning of each meeting, as a standing item of the Agenda.

Members must absent themselves from the meeting during discussion of any item for which they have declared a conflict of interest. Any such absence shall be recorded in the Minutes of the meeting.

No member shall provide written or verbal comment on any application for which they have a conflict of interest.

Confidentiality

ACEC members, UTS staff and others privy to the content of applications and the deliberations of the ACEC shall observe the confidential nature of those documents and discussions. Members wishing to seek advice on confidential matters may approach the Chair or the Research Ethics Manager who shall assist them so they can proceed without breaching confidentiality (2.2.22).

Animal Ethics Committee Executive

The ACEC may establish an Executive. The Executive:

- Must include the ACEC Chair, the Animal Facility Manager, the Research Ethics Manager or nominee and at least one member from Category C or D.
- May be delegated to approve minor amendments to approved projects or activities, for ratification at the next ACEC meeting. The types of activity that would be a minor amendment include a change to an approved project where the proposed change is not likely to cause harm to the animals (including pain and distress) and does not increase the number of animals used.
- Must not approve new applications (2.2.23).

Meeting procedures

At least one member from each of the membership categories A, B, C and D must be present at meetings to establish a quorum for the conduct of a meeting, and must be present throughout the meeting. Categories C and D together must represent at least one-third of those members present (2.2.25).

Meeting procedures shall include:

- Timely distribution of papers to ACEC members in advance of a meeting to enable members to be fully informed;
- The conduct of quorate ACEC meetings, including circumstances where a face-to-face meeting is not possible—for example, through the use of videoconferencing and web-conferencing or, in special circumstances, teleconferencing;
- Management of any perceived or actual conflicts of interest that may arise;
- Frequency of meetings, which should be sufficient to allow for effective functioning of the ACEC;
- Review and approval of new and ongoing activities as per Clauses 2.3.3–2.3.16 of the Code (2.2.26).

The ACEC may appoint a sub-committee to investigate matters that are not readily dealt with under procedures which apply to the full committee. A sub-committee of the ACEC shall:

- Consist of at least one member from either Category A or B, and at least one member from either Category C or D, and may include any other person deemed appropriate by the ACEC (e.g. Research Ethics Manager, Animal Facility Manager, etc.);
- Usually be advisory only unless it is required to act urgently in order to avoid or minimize pain or distress to animals, or if authorized otherwise by the full ACEC;
- Be permitted to communicate directly with other parties as deemed reasonably necessary to achieve its goals;
- Have its decisions reviewed and ratified by the full ACEC at its next meeting;
- Remain in operation until its business has been completed after which it shall be disbanded.

All members must have the opportunity to contribute to the decision-making process unless there is a conflict of interest. If the member is unable to attend in person they may comment on a protocol in writing before the meeting.

The ACEC may delegate authority to the Chair to approve changes in personnel in an approved project out of session with subsequent ratification by the Committee.

Investigators should have an opportunity to respond to any concerns raised by the ACEC before a final decision is made.

Communication

The ACEC shall clearly communicate its decisions, the reasons for its decisions and any conditions attached to an approval to investigators in writing as promptly as possible (2.2.27).

The ACEC shall consider face-to-face meetings with applicants to resolve issues (2.2.28).

Investigators must be informed of the ACEC's decision in writing.

Complaints and non-compliance

For the purposes of this section, the term 'complaints' shall include concerns relating to regulatory non-compliance as well as complaints relating directly to the wellbeing of animals used for scientific purposes in projects approved by the UTS ACEC. Complaints may relate to breaches of the Code or state and territory legislation relevant to safeguarding the wellbeing of animals used for scientific purposes.

Complaints may be raised by any person or group, including investigators, animal carers, the ACEC, ACEC members, students, employees and members of the public. Complaints may relate to the activities of any party or person involved in the care and use of animals, including investigators, animal carers, the ACEC and governance officials (Code Section 5 preamble).

Complaints may relate to:

- The care and use of animals by the institution, including conscientious objection in the case of teaching activities;
- The ACEC process of review of an application or report, including resolution of disagreements between ACEC members, between the ACEC and investigators, and between the ACEC and the institution;

- The process for independent external review;
- Non-compliance with the Code or breaches of relevant state or territory legislation by any party or person involved in the care and use of animals including investigators, animal carers, the ACEC, governance officials, and external parties subject to agreements described in Clauses 2.6.3 and 2.6.6 (5.1).

The handling of complaints shall:

- Give priority consideration to the wellbeing of the animals, and ensure that activities with the potential to adversely affect animal wellbeing cease immediately (5.2[i]);
- Follow the procedures set out below in these Terms of Reference (5.2 [ii-iv]);
- Ensure fair, prompt, timely, effective, confidential processes that accord with procedural fairness, the principles of natural justice and protection of whistleblowers (5.2 [v]);
- Be in compliance with relevant UTS policies and procedures;
- Ensure appropriate reporting to and consultation with the institution, the ACEC, state or territory government authorities, and any other relevant bodies (5.2 [vi]);
- Ensure that access to relevant procedures is available to complainants and all other stakeholders (5.2 [vii]).

The procedure for handling complaints shall be as follows:

- Complaints should be referred in the first instance to the Research Ethics Manager and the ACEC Chair who will advise the complainant on a proposed course of action including the need to consult the ACEC. If the complainant is dissatisfied with the proposed course of action, an alternative approach may be negotiated. If an agreement on a course of action cannot be reached, the complainant may take the matter to the Director, Research and Innovation Office or to the DVCR;
- The complainant should also be advised of a person or agency external to UTS to whom a person can take a complaint that has not been resolved by internal processes (5.8) and that any person can report alleged breaches of legislation to relevant state or territory government authorities (5.11).

UTS through the Research Ethics Manager shall:

- Where complaints relate to activities that have the potential to adversely affect animal wellbeing, ensure the activities cease immediately (5.4[i]);
- Where complaints relate to activities that would normally require ACEC approval, ensure the complaints are referred to the ACEC to investigate whether such activities are conducted in accordance with ACEC approval (5.4[ii]);
- Where complaints raise the possibility of 'research misconduct', as described in the Australian Code for the responsible conduct of research, ensure the complaint is handled in accordance with the UTS processes for dealing with breaches and research misconduct (5.4[iii]);
- Where complaints allege misconduct that falls outside the range of 'research misconduct', as described in the Australian code for the responsible conduct of research, ensure the complaint

is handled in accordance with UTS processes for dealing with other forms of misconduct (5.4[iv]);

- Where projects involve more than one institution and/or ACEC, shall ensure prompt communication with the other institution(s) on all relevant matters (5.3).

Complaints may be made anonymously although it must be recognized that anonymity can hinder the investigation of complaints in some situations.

Investigation of complaints may involve:

- Steps to establish that the complaint is not vexatious or without genuine foundation;
- Consultation with other parties if deemed necessary to establish facts or obtain input considered likely to assist in reaching a fair resolution. Such consultation will be with the approval of the complainant and confidentiality will be observed wherever possible.

Complaints deemed to be vexatious or without genuine foundation will not be investigated further.

When a breach of the Code is detected, the ACEC must ensure that:

- Actions are taken to ensure that animal wellbeing is not compromised, the issue is addressed promptly, and activities that have the potential to adversely affect animal wellbeing cease immediately. Actions may include suspending or withdrawing approval for the project.
- Actions are taken to address the issues in consultation with the person(s) involved
- When considered necessary, such matters are referred to DVCR for action
- Non-compliance receives appropriate follow-up (2.3.25, 5.9).

Following the ACEC's investigation of complaints referred to it by the institution, the ACEC:

- Must ensure that, where activities are conducted in accordance with an ACEC approval, the activities are reviewed in consultation with all relevant people to ensure that the reason for the complaint is addressed. The ACEC may decide that modification to a project or activity is required, or an approval for a project or activity is suspended or withdrawn (5.5[i])
- Should ensure that, where activities are not conducted in accordance with ACEC approval, the matter is referred back to the institution through the Research Ethics Manager for action (5.5[ii]).

In situations where a Non-Compliance requires urgent action to minimise adverse effects on animal wellbeing, responsibility for ensuring an appropriate response will be delegated automatically to the Chair, the Animal Facility Manager or consultant veterinarian until such time as the matter can be considered by the full Committee. The matter must be considered by the full Committee as soon as reasonably practicable.

In cases where alleged breaches have had a significant impact on animal wellbeing, the Research Ethics Manager shall ensure that appropriate notification is made to the relevant state or territory government authority (ies) (5.12).

Addressing non-compliance with the Code or relevant legislation should include referral to UTS's Animal researcher training programs and other measures deemed appropriate by the ACEC that

encourage and support compliance with the Code and emphasise that behaviours that compromise compliance are not tolerated (5.9).

The Committee shall inform an investigator in writing of its intention to take appropriate action, detailing its reasons for taking such action.

In the case of serious or repeated breaches, the matter will be referred to the DVCR who may recommend to the Vice-Chancellor to refer the matter to the Animal Research Review Panel or the Director General of NSW Department of Primary Industries for investigation.

Complaints will be received on the understanding that complainants will comply with all reasonable requests to assist in the investigation of their complaint and that should a complainant choose not to comply with such requests, further investigation or resolution of their concerns may be delayed or may not be possible.

The Research Ethics Manager shall ensure that the Ethics Secretariat maintains records of complaints (including those deemed to be vexatious or without genuine foundation) or breaches of the Code (5.10) or relevant State or territory legislation. These records should include the identity of the complainant (if known), the date and details of the complaint or breach, copies of correspondence and meeting notes, and outcomes.

Complaints about ACEC process

Where complaints concerning the process of review of an application or report cannot be resolved by communication between the complainant and the ACEC, the complaint should be referred to the DVCR for review of the process followed by the ACEC. Following this review, the ACEC may need to review its process in reaching its decision regarding the application or report, and re-evaluate its decision in light of the reviewed process. The ultimate decision regarding the ethical acceptability of an activity lies with the ACEC and must not be overridden (2.2.29, 5.6).

Upon the receipt of a complaint, the Research Ethics Manager shall inform the Chair and shall propose a course of action to the ACEC. The course of action may include referral of the matter to the Research Integrity Manager in the DVCR's office for further investigation or consideration and shall include steps to establish the validity of the complaint to ensure it is not vexatious or without genuine foundation.

Records

The Ethics Secretariat must ensure that records related to the ACEC's business are maintained, so that the following items of information are readily available:

- A register of all applications (including amendments) to the ACEC, including the outcomes of deliberations;
- Details of applications to be maintained in records include:
 - Name of responsible institution
 - Project identification number
 - Principal investigator(s)
 - Short title of project
 - Ethical approval or non-approval with date
 - Date(s) designated for review
 - Details of monitoring procedures
 - Animal species and numbers used

- Details of intended site of the holding and research on animals
 - Comments made by Committee members about protocols
 - Investigators' responses to comments by ACEC members
 - Relevant correspondence
- Minutes that record decisions and other aspects of the ACEC's operation;
 - Records of inspections conducted by the ACEC that include the names of attendees, observations, any identified problems, recommended actions, ongoing or outstanding issues, and outcomes (2.2.30 and 2.3.22);

Animal care staff shall have access to records of approved projects and reports where appropriate and in consultation with the ACEC (2.2.31).

Documentation

The Ethics Secretariat under the supervision of the Research Ethics Manager shall, in consultation with the ACEC, develop procedures for:

- Application for ACEC approval to commence a project that addresses the governing principles of the Code and in accordance with Section 2.7 of the Code;
- Follow-up review of an approved project at scheduled times and when circumstances trigger additional follow-up review, including proposed amendment to an approved project or activity, review of annual progress of an ongoing project or activity and unexpected adverse events
- Reporting on an approved project or activity that has been completed or discontinued (2.2.32).

The Ethics Secretariat under the supervision of the Research Ethics Manager shall conduct an annual review of the operation of the ACEC to ensure that it is effective and consistent with the Code and institutional policies. The review must include:

- An assessment of the ACEC's annual report;
- A meeting with the ACEC Chair;
- An assessment of the effectiveness of processes regarding complaints and non-compliance (2.2.1[v], 2.2.37, 2.1.9 [iii]).

Research involving UTS and one or more other institutions or parties

Research involving the use of animals at one or more institutions in addition to UTS must be conducted in accordance with the NSW Animal Research Review Panel Guideline '[Collaborative Research](#)' and clauses 2.6.3 to 2.6.8 of the Code. This will involve ensuring that:

- All parties involved are aware of, and can meet, their respective responsibilities under the requirements of the Code (2.6.4 [i]);
- A project does not commence before each ACEC approves, or the delegate ('host') ACEC approves, activities to be conducted by members of its institution. Each ACEC should be responsible for approval and monitoring of animal care and use that occurs at the institution for which it acts (2.6.4 [ii]);

- The responsible ACECs are aware of all aspects of the proposed use of animals, and consider the cumulative effects on the wellbeing of the animals involved (2.6.4 [iii]);
- The responsible ACECs can inspect the animals so that all phases of the project are monitored, including any animal transport between sites (2.6.4 [iv]);
- Animals will receive appropriate care in all phases of the project, including any animal transport between sites (2.6.4 [v]);
- Clear communication channels are established between all ACECs and all investigators (2.6.4 [vi]);
- All parties understand the circumstances under which they may withdraw from the agreement (2.6.3 [iii]).

UTS and the other institution(s) may agree to one ACEC (the 'delegate' or 'host' ACEC) 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 ACEC (2.6.5). The employing institution would, however, continue to have authority over its employee's actions and would be responsible, in terms of vicarious liability, for any acts of its employee, which contravene the NSW Animal Research Act 1985.

Procedures to be followed when research involving the use of animals at one or more institutions in addition to UTS shall include:

- The delegation of approval, monitoring and reporting of all phases of the project to the 'host' institution's ACEC (also referred to as the 'delegate ACEC' in the Code);
- The establishment of clear communication channels between all involved ACECs and investigators;
- Formal agreement between UTS and the other institution(s) that all parties involved are aware of and can meet their respective responsibilities under the requirements of the Code and relevant legislation; unnecessary duplication of processes should be avoided (2.6.6);
- Agreement by all researcher(s) and their institution(s) to abide by the procedures and any decisions of the UTS ACEC;
- Provision by the researcher(s) of a copy of the final version of the application submitted to the host institution's ACEC, together with a copy of their letter of approval and any other relevant correspondence;
- Provision to the UTS ACEC by the researcher(s) of a copy of any reports to the other institution's ACEC;
- Prompt notification by the researcher(s) to the UTS ACEC of any unexpected adverse events;
- Communication to ensure prompt notification of all ACECs of non-compliant activities (2.6.7).

Reporting (Code 2.2.18 [iii])

The ACEC Chair and the Research Ethics Manager shall meet twice yearly with the DVCR to report on the activities of the ACEC. The Chair may directly notify or meet with the DVCR on matters relating to the ACEC at other times at his or her discretion.

The ACEC must submit a written report on its operations at least annually to the Vice-Chancellor through the DVCR (2.3.28).

The report should advise on:

- The number of meetings held;
- The numbers and types of projects assessed, and approved or rejected;
- Results of inspections and other matters relevant to the physical facilities for the care and use of animals;
- Actions that have supported the educational and training needs of ACEC members and people involved in the care and use of animals;
- Outcomes or initiatives that have helped advance the 3Rs;
- Reports of any formal complaints received whether relating to animal wellbeing or ACEC processes and whether originating from within or outside UTS;
- Matters such as breaches of the Code or Unexpected Adverse Events where the outcome may have broader implications for the University's use of animals for scientific purposes or its ability to maintain compliance with the NSW Animal Research Act, the NSW Animal Research Regulation and the Code;
- Administrative or other difficulties experienced;
- Any matters that may affect the institution's ability to maintain compliance with the Code and, if appropriate, suitable recommendations (2.3.29);
- As part of the ACEC accreditation licence, an annual report to the NSW Animal Research Review Panel must be submitted by 31st March each year.
- In addition, annual reports to State and Territory licencing bodies should be submitted by the Ethics Secretariat by the relevant deadline.