

SYDNEY LOCAL HEALTH DISTRICT

ANIMAL WELFARE COMMITTEE (AWC)

TERMS OF REFERENCE and OPERATING GUIDELINES

1. Purpose of the Committee

To undertake ethical review and to provide ethical oversight and advice regarding:

- research involving animals
- teaching involving animals
- any other relevant activities

undertaken within the following facilities of the Sydney Local Health District (SLHD):

- RPAH Animal House
- Institute of Academic Surgery
- RPA Surgical & Robotic Training Institute
- ANZAC Research Institute – Molecular Physiology Unit
- ANZAC Research Institute – Translational Research Facility
- Australian National Baboon Colony (ANBC)

and the following affiliated institutions:

- Heart Research Institute
- Centenary Institute of Cancer Medicine and Cell Biology.

2. Responsibilities

2.1 To review research involving animals and the ethical aspects of undergraduate and postgraduate teaching activities involving animals undertaken within the facilities listed in Section 1 or by staff attached to those facilities in accordance with:

- *The Australian code for the care and use of animals for scientific purposes (8th edition, 2013)* (hereinafter referred to as “the Code”)
- The conditions on the SLHD’s Certificate of Accreditation as an Animal Research Establishment

- The conditions on the SLHD's Animal Supplier's Licence
 - Other legislated and statutory requirements.
 - Prevailing guidelines issued by the NSW Animal Research Review Panel (ARRP)
- 2.2 To approve only those research studies and teaching uses for which animals are essential and justified and which conform to the *Code*, taking into consideration factors such as ethics, the impact on the animal(s) and the anticipated scientific and/or educational value.
- 2.3 To approve, in advance, the immediate use of animals where such use is required for the diagnosis of unexplained and severe disease outbreaks, or morbidity/mortality, in animals or humans.
- 2.4 To review guidelines for the care of animals that are bred, held and used for scientific purposes within the facilities listed in Section 1.
- 2.5 To monitor the acquisition, transportation, production, housing, care, use and fate of animals used for research and teaching within the facilities listed in Section 1.
- 2.6 To authorise the emergency treatment or euthanasia of any animal. This function may be delegated to a registered Veterinary Practitioner member of the Committee
- 2.7 To examine and comment on all plans and policies within the facilities listed in Section 1 that may affect the welfare of animals used for scientific purposes. This includes the review of building and land management plans which relate to facilities to house animals or through which animals will passage.
- 2.8 To recommend to the SLHD Chief Executive any measures needed to ensure that the standards of the *Code* are maintained.
- 2.9 To perform all other duties required by the *Code*.
- 2.10 To provide ethical advice regarding any other relevant activities, referred to it by:
- SLHD Chief Executive
 - administrative officers, clinical, research and/or teaching staff of the facilities listed in Section 1.

- SLHD committees including but not limited to Committees investigating incidents or events impacting on or impacted by animal research

3. Status of the Committee within the SLHD

3.1 The SLHD Animal Welfare Committee is a committee of the SLHD with delegated authority to make decisions concerning the ethical acceptability of research proposals and other activities involving the use of animals. Under the Terms of Reference the Committee, when constituted in accordance with the *Code*, has authority to:

- approve proposals
- approve proposals subject to modification
- defer and request major modifications to proposals
- reject proposals
- monitor approved studies
- approve amendments to approved studies
- suspend approved studies
- withdraw ethical approval from a study
- withdraw animal use privileges from an individual or group of investigators or facility where there are reasonable grounds for such action
- deal with complaints regarding animal welfare issues.

3.2 The members of the Committee, acting in good faith in the fulfilment of their responsibilities, shall be indemnified by the SLHD or another organisation nominated by SLHD to assume that responsibility.

4. Reporting to the SLHD Chief Executive

4.1 The minutes of the Committee's meetings shall be forwarded to the SLHD Chief Executive, on a monthly basis following confirmation.

4.2 The Committee shall provide an annual report at the end of each calendar year which shall include the following:

- Committee membership and any changes throughout the year

- Committee meetings and facility inspections
- The number and types of studies assessed and approved or rejected
- The physical facilities for the care and use of animals within the facilities listed in Section 1
- The activities which have supported the educational needs of Committee members, researchers and teachers, and animal carers
- Any administrative or other difficulties being experienced
- Any matters that may affect the ability of the facilities listed in Section 1 to maintain compliance with the *Code* and, if necessary, the provision of suitable recommendations
- Examples of the implementation of the 3Rs: Replacement, Reduction and Refinement.

4.3 The Committee may from time to time:

- bring to the attention of the SLHD Chief Executive issues of significant concern
- refer any matter of concern requiring legal opinion to the SLHD Chief Executive
- seek the assistance of the SLHD Chief Executive in resolving complaints and disputes
- seek rulings from the SLHD Chief Executive on policy issues
- make recommendations to the SLHD Chief Executive concerning any other matters which it considers relevant.

5. Composition of the Committee

5.1 The composition of the Committee shall be in accordance with the stipulations of the *Code*, ie:

- A Chairperson
- Category A – a person with qualifications in veterinary science and experience relevant to the activities of the institution
- Category B – a suitably qualified person with substantial recent experience in the use of animals in scientific or teaching activities

- Category C – a person with demonstrable commitment to, and established experience in, furthering the welfare of animals, and who is not employed or otherwise associated with the institution
 - Category D – a person who is both independent of 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.
- 5.2 Category C plus Category D members shall make up at least one-third of the Committee's membership.
- 5.3 The Committee may from time to time co-opt individuals with expertise relevant to specific areas of research activity.
- 5.4 The SLHD Chief Executive shall appoint an ex officio Executive Officer to the Committee.
- 5.5 Members of the Committee may be reimbursed for reasonable direct costs incurred in attending meetings of the Committee.

6. Appointment of Members

- 6.1 The Chairperson shall be appointed by the SLHD Chief Executive following consultation with the Committee and with other senior institutional officers, as deemed appropriate.
- 6.2 Category A and B positions and people from the facilities listed in Section 1 who are responsible for the routine care of animals shall be nominated by the relevant facility head.
- 6.3 Applications for vacant Category C and D positions may be sought through the Animal Research Review Panel. A selection committee (consisting of the Chairperson, the Executive Officer and at least one other Committee member) shall interview short-listed applicant(s) and make a recommendation to the SLHD Chief Executive. If no suitable applicant is found, the Committee shall seek further candidates.
- 6.4 Upon appointment, each member shall be required to sign a statement undertaking:
- that he/she accepts the Committee's Terms of Reference
 - that all matters of which he/she becomes aware during the course of his/her work on the Committee will be kept confidential
 - that any conflicts of interest which exist or may arise during his/her tenure on the Committee will be declared

- that he/she has not been subject to any criminal conviction or disciplinary action which may prejudice his/her standing as a Committee member.
- 6.5 Newly appointed members shall be provided with a copy of the *Code* and any other information relevant to the Committee's operation.
- 6.6 Throughout their tenure, members shall be given the opportunity to attend conferences and workshops relevant to the work and responsibilities of the Committee, which are organised by the National Health & Medical Research Council, by Industry & Investment NSW and, at the discretion of the SLHD Chief Executive, by other relevant bodies.

7. Terms of Appointment

- 7.1 The term of appointment for Committee members shall normally be three years.
- 7.2 The term of appointment for the Chairperson shall normally be four years.
- 7.3 Appointments may be renewed. Recommendations for renewal of appointment shall be made to the SLHD Chief Executive by the Chairperson.

8. Establishment of an Executive Committee

- 8.1 The Committee may establish an Executive Committee to deal with minor matters between Committee meetings.
- 8.2 The composition of the Executive Committee shall include the Chairperson, a member from Category A and at least one member from Category C or D. Wherever possible, the Executive Officer shall participate in the Executive Committee's deliberations to record its decisions.
- 8.3 The Executive Committee shall meet either in person, by telephone, via video conferencing or, where appropriate, via email communication.
- 8.4 The Executive Committee cannot approve new applications or the ongoing approval for a project (via consideration of an annual report). Applications for new projects, and ongoing approvals for existing projects, must only be considered and approved by the AWC at quorate meetings. Under exceptional circumstances the Executive may briefly extend a project until the next quorate meeting of the AWC should the project approval lapse between meetings.
- 8.5 Decisions made by the Executive Committee shall be ratified by the next Committee meeting.

9. Meetings

- 9.1 Committee meetings shall normally be held at least ten (10) times per year at approximately monthly intervals from February to November.
- 9.2 Meeting dates and agenda closing dates shall be published appropriately.
- 9.3 For the purposes of reaching decisions regarding research protocols or amendments, a quorum shall exist when a representative of Categories A, B, C and D is present (see 5.1 and 5.2 above).

10. Procedures

- 10.1 Research proposals shall be submitted to the Committee on the approved application form.
- 10.2 In order to be considered at a scheduled meeting, research proposals and other correspondence shall be received at the RPAH Research Ethics and Governance Office before close of business on the advertised closing date.
- 10.3 New research proposals will firstly be considered at a scheduled Committee meeting. Studies currently approved at another institution may be granted interim approval pending such a meeting.
- 10.4 The Committee shall have the option of inviting an investigator to attend the Committee meeting at which his/her proposal will be reviewed to discuss it with the Committee.
- 10.5 The Committee shall approve proposals which conform to the *Code* for a period of one year. Subject to receipt of satisfactory progress reports, approved studies will normally be approved for two further years on an annual basis. However, the Committee may take account of the nature of the study, the number of years for which the study is funded, any milestones or stages outlined in the proposal, and any Deeds of Agreement between the facilities listed in Section 1 and the funding body when deciding on the maximum duration of approval for individual studies.
- 10.6 Amendments to approved studies shall normally be considered at a scheduled Committee meeting.
- 10.7 A Committee member involved in a research proposal under consideration shall absent him/herself from the meeting during the discussion and until a decision has been reached. The Committee shall continue to operate with a quorum when such a Committee member is temporarily absent.
- 10.8 The Committee shall reach decisions by consensus after all members have been given the opportunity to express their views. In the event that a consensus cannot be reached, a decision may be taken by voting (show of hands) after members have been allowed a period of time to review their positions, followed by further discussion. Dissenting views shall be recorded in the minutes.
- 10.9 The Committee shall review annual progress reports on approved studies. If satisfactory, the Committee will approve continuation of the study. In the case of breeding protocols, the Committee will require six-monthly reports. Neither the Executive Committee nor a non-quorate Committee can provide ongoing approval for a project (via consideration of an annual report) under the Code, or subsequently make a decision to recommend the issuing of an animal research authority under the Act.

10.10 The Committee shall review completion reports on approved studies.

10.11 Between scheduled Committee meetings an Executive Committee may consider:

- matters arising from the minutes of the previous meeting(s), including final approval of conditionally approved studies or amendments
- minor amendments to approved studies or activities. A minor amendment is defined as a change to an approved study or activity where the proposed change, in comparison to what has already been approved, has a minor or positive impact on:
 - animal welfare and
 - the anticipated scientific or educational value and the likelihood of meeting the study's objectives
- any other administrative and/or minor matters requiring attention before the next scheduled Committee meeting.

The Executive Committee cannot approve new applications or the ongoing approval for a project (via consideration of an annual report). Under exceptional circumstances the Executive may briefly extend a project until the next quorate meeting of the AWC should the project approval lapse between meetings.

11. Responsibilities of the Chairperson

The Chairperson shall:

- ensure that the Committee operates in accordance with the principles and requirements of the *Code*, the relevant policies of the facilities listed in Section 1 and the agreed Committee procedures
- advise the SLHD Chief Executive regarding the level of resourcing required by the Committee
- represent the Committee in any negotiations with the SLHD Chief Executive or other designated official.

12. Responsibilities of the Executive Officer

12.1 The Executive Officer shall be responsible for the preparation of the meeting agendas, which shall be circulated at least one week before the meeting.

- 12.2 The Executive Officer shall be responsible for the preparation of the minutes of meetings, and of correspondence arising from the minutes.
- 12.3 The Executive Officer shall endeavour to notify investigators of the Committee's decisions within one week, and no more than ten days, after each meeting.
- 12.4 The Executive Officer shall be responsible for the keeping of Committee records, including the SLHD AWC Project Database, the protocol files and all other Committee files, and ensure that they are available for review by the SLHD and authorised external reviewers.
- 12.5 The Executive Officer shall be responsible for forwarding minutes of Committee meetings to the SLHD Chief Executive.
- 12.6 The Executive Officer shall be responsible for drafting annual reports to the National Health & Medical Research Council and the Industry & Investment NSW. Such reports shall be reviewed and approved by the Chairperson before despatch.
- 12.7 The Executive Officer shall be responsible for drafting licence applications to the Industry & Investment NSW. Such licence applications shall be reviewed and approved by the Chairperson and, where appropriate by the SLHD Chief Executive, before despatch.
- 12.8 The Executive Officer shall undertake such other tasks as are requested by the Chairperson and/or the Committee.

13. Monitoring

- 13.1 The Committee shall normally require progress/completion reports on approved studies from chief investigators on an annual basis. In some circumstances, the Committee may require more frequent reports and/or such other information as deemed necessary to ensure the safety and well-being of the animals.
- 13.2 Requests for reports, accompanied by the approved report forms, shall be forwarded to chief investigators by the Executive Officer approximately two weeks before the due date.
- 13.3 All reports from chief investigators on active or completed studies shall be included in the Committee agenda.
- 13.4 Reminder letters shall be sent by the Executive Officer each month to chief investigators whose reports have not been received by the due date.

13.5 The Committee shall normally require reports from animal house managers on animal usage within their facilities on a monthly basis. Such reports will be included in the Committee agenda.

13.6 The Committee shall normally inspect all animal holding facilities under its jurisdiction at least twice annually. Such inspections shall be undertaken by two Committee members not associated with the facility being inspected. Written reports on the outcome of the inspections will be included in the Committee agenda.

14. Complaints

A. Complaints from independent people who are not associated with research

14.1 The complainant will be asked to put their complaint in writing.

14.2 The Chairperson of the Committee will review the complaint.

14.3 The complaint will be forwarded with the agenda papers for consideration at the next scheduled Committee meeting.

14.4 If the Committee is unable to resolve the matter or if the complainant is dissatisfied with the response, the complaint will be forwarded to the SLHD Administration for resolution.

14.5 If the SLHD Administration is unable to resolve the matter or if the complainant is dissatisfied with the response, the Committee will facilitate a review of the matter by the Animal Research Review Panel.

B. Complaints from staff or students within the facilities listed in Section 1

14.6 The complainant will be asked to put their complaint in writing.

14.7 The Chairperson of the Committee will review the complaint.

14.8 The complaint will be forwarded with the agenda papers for consideration at the next scheduled Committee meeting.

14.9 If the Committee is unable to resolve the matter or if the complainant is dissatisfied with the response, the complaint will be forwarded to the SLHD Administration and, if appropriate, the Administration of the relevant facility for resolution.

14.10 If the SLHD Administration and, if appropriate, the Administration of the relevant facility are unable to resolve the matter or if the complainant is dissatisfied with the response,

the Committee will facilitate a review of the matter by the Animal Research Review Panel.

See also the following Policy Directives:

- SLHD_PD2013_014 : Complaints Management – Policy and Procedures
- PD2016_046 : Resolving Workplace Grievances

C. Disputes between investigators / teachers and the Committee

- 14.11 The complainant will be asked to put their complaint in writing.
- 14.12 The Chairperson of the Committee will review the complaint.
- 14.13 The complaint will be forwarded with the agenda papers for consideration at the next scheduled Committee meeting.
- 14.14 If the Committee is unable to resolve the matter or if the complainant is dissatisfied with the response, the complaint will be forwarded to the SLHD Administration and, if appropriate, the Administration of the relevant facility for resolution.
- 14.15 If the SLHD Administration and, if appropriate, the Administration of the relevant facility are unable to resolve the matter or if the complainant is dissatisfied with the response, the Committee will facilitate a review of the matter by the Animal Research Review Panel.

See also the following Policy Directives:

- SLHD_PD2013_014 : Complaints Management – Policy and Procedures
- PD2016_046 : Resolving Workplace Grievances

D. Serious disagreements between members of the Committee

- 14.16 The Committee member will be asked to put their concern in writing.
- 14.17 The Chairperson of the Committee will review the member's concern.
- 14.18 The concern will be forwarded with the agenda papers for consideration at the next scheduled Committee meeting.

- 14.19 If the Committee is unable to resolve the disagreement or if the member is dissatisfied with the response, the matter will be forwarded to the SLHD Administration for resolution.
- 14.20 If the SLHD Administration is unable to resolve the matter or if the member is dissatisfied with the response, the Committee will facilitate a review of the matter by the Animal Research Review Panel.

E. Disagreements between the Committee and the SLHD Administration

- 14.21 The Committee will put its concern in writing to the SLHD Chief Executive.
- 14.22 The Chairperson will meet with the SLHD Chief Executive to discuss the Committee's concerns.
- 14.23 If the Committee is dissatisfied with the SLHD Chief Executive's response, the Committee will seek a review of the matter by the Animal Research Review Panel.

15. Sanctions

15.1 In the event of a serious breach of the guidelines outlined in the *Code*, the Committee may take any of the following actions:

- suspend the study and withdraw ethical approval, if the study is ongoing
- review the ethical approval of all research being undertaken by the investigator(s) in question
- notify the relevant head(s) of department(s) and institution(s), the SLHD Chief Executive, and the sponsor/funding body
- notify any other animal welfare committees which have approved the study.

15.2 In the event of suspected/alleged scientific misconduct as defined in the *Australian Code for the Responsible Conduct of Research*, the Committee shall refer the matter to the SLHD Chief Executive for action in accordance with the SLHD's policy SLHD_PD2014_008 : Responding to Allegations of Research Misconduct. In those instances where the relevant research study is ongoing, the Committee shall also take action as outlined in 15.1 above.