



# Wildlife Animal Ethics Committee Terms of Reference and Operating Procedures (TOROPs) – July 2022



#### Contents

| 1. Introduction  | 4  |
|--|----|
| 2. Background  | 4  |
| 3. Scope of responsibilities   | 4  |
| 3.1 Responsibilities of the Wildlife AEC chairperson                 | 4  |
| 3.2 Responsibilities of the Wildlife AEC members                     | 4  |
| 3.3 Responsibilities of the Wildlife AEC                             | 5  |
| 4. Wildlife AEC membership, appointments, and support                | 6  |
| 4.1 Membership   | 6  |
| 4.1.1 Chairperson  |    |
| 4.2 Selection, appointment, and obligations                          |    |
| 4.2.1 Primary/secondary categories of membership                     | 7  |
| 4.2.2 Confidentiality  |    |
| 4.4 Support to the Wildlife AEC                                      |    |
| 4.5 Wildlife AEC Executive   |    |
| 5. AEC meetings  |    |
| 5.1 Ordinary and extraordinary meetings                              |    |
| 5.2 Meetings schedule  |    |
| 5.3 Quorum   |    |
| 5.4 Conflict of Interest   |    |
| 6. Review and assessment of new projects                             |    |
| 6.1 Assessment and approval  |    |
| 6.1.1 Preliminary assessment   | 11 |
| 6.1.2 Wildlife AEC assessment of applications                        |    |
| 6.3 Duration of approval   |    |
| 6.3.1 Project extension  |    |
| 7. Personnel training, competency, and standard operating procedures | 13 |
| 7.1 Personnel training   | 13 |
| 7.2 Competency of personnel  | 13 |
| 7.3 Standard Operating Procedures (SOPs)                             | 14 |
| 8. Notification of Wildlife AEC decisions                            | 14 |
| 9. Amendments to approved projects or activities                     | 15 |
| 10. Monitoring the care and use of animals                           |    |
| 11. Management of issues / adverse events                            |    |
| 11.1 Unexpected Adverse Event Report (AER)                           |    |
| 11.2 Summary reports and the management of incidents                 |    |
| 12. Standard reporting of activities by the CI to the Wildlife AEC   |    |

| 12.1 Project Completion Report (PCR)  | 17 |
|---|----|
| 12.2 Annual Animal Use Review (AAUR)  | 17 |
| 12.3 Other reports  | 18 |
| 13. Complaints and non-compliance relating to the care and use of animals scientific purposes |    |
| 13.1 Complaints concerning the care and use of animals by institutions                        | 18 |
| 13.2 Complaints concerning the Wildlife AEC process   | 19 |
| 13.3 Complaints concerning the process for independent external review                        | 19 |
| 13.4 Non-compliance   | 19 |
| 14. Annual reports and independent external reviews   | 21 |
| 14.1 Annual report  | 21 |
| 14.2 Independent external review  | 21 |
| Appendix 1  | 23 |
| Glossary  | 23 |
| Appendix 2  | 28 |
| Major vs minor amendments - Guidelines  | 28 |
| Important disclaimer  | 30 |

#### 1. Introduction

The following Terms of Reference & Operating Procedures (TOROPs) have been endorsed by the Department of Primary Industries and Regional Development (DPIRD) and the Western Australian Wildlife Animal Ethics Committee (Wildlife AEC).

They should be read in conjunction with the <u>Australian code for the care and use of</u> <u>animals for scientific purposes 8<sup>th</sup>edition 2013 (the Code)</u>, the <u>Animal Welfare Act 2002</u> (the Act), and related DPIRD policies. A glossary of terms is provided in Appendix 1.

In the event of any conflict of interpretation, the provisions of the Act and the Code will prevail.

The TOROPs are publicly available upon request and will be published on DPIRD's website and other DPIRD communication channel DPIRD deemed suitable.

#### 2. Background

The ability of environmental scientists to use animals for scientific purposes is subject to licensing (Scientific Use Licence, SUL) under the Act. A condition of the SUL is that animals must not be used for scientific purposes unless such use complies with the Code.

The Wildlife AEC is a statutory body that has been established by DPIRD and constituted in accordance with the requirements laid down in the Code to address this requirement.

All projects and activities undertaken by environmental scientists (who don't have access to a properly constituted Animal Ethics Committee) in Western Australia that involve the care and use of animals for scientific purposes must:

- Be subject to ethical review, approval, and monitoring by the Wildlife AEC.
- Commence only after approval has been granted by the Wildlife AEC.
- Be conducted in accordance with Wildlife AEC approval.
- Cease if approval from the Wildlife AEC is suspended or withdrawn.
- Submit an annual report, including the number of animals used to the Wildlife AEC.

#### 3. Scope of responsibilities

#### 3.1 Responsibilities of the Wildlife AEC chairperson

The chairperson (Chair) is responsible for impartially guiding the operation of the AEC, resolving conflicts of interest related to the business of the AEC, and representing the AEC in any negotiations with the DPIRD's management.

#### 3.2 Responsibilities of the Wildlife AEC members

Each member is responsible for deciding whether, in their own judgement, an application or other matter under consideration by the AEC is ethically acceptable and meets the requirements of the Code.

To fulfil this responsibility, members should:

- Be familiar with the Code, Wildlife AEC Terms of Reference & Operating Procedures, and other policies and guidelines relevant to the business of the AEC.
- Provide opinions on the ethical acceptability of applications and other matters under consideration by the AEC.

#### 3.3 Responsibilities of the Wildlife AEC

The Wildlife AEC's primary responsibility is to DPIRD's Director General (DG) to ensure, on behalf of DPIRD for which it acts, that all activities relating to the care and use of animals for scientific purposes are conducted in compliance with the Code.

#### The Wildlife AEC shall:

- Apply the principles that govern the use of animals for scientific purposes:
  - Use animals only when it is justified.
  - Support the wellbeing of the animals involved.
  - o Avoid or minimise harm, including pain and distress, to those animals.
  - Apply high standards of scientific integrity.
  - Apply Replacement, Reduction and Refinement (the 3Rs) at all stages of animal care and use.
- Review new applications for projects and approve only those projects that are ethically acceptable and conform to the requirements of the Code.
- 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.
- Conduct follow-up review of approved projects and activities and allow the continuation of approval for only those projects and activities that are ethically acceptable and conform to the requirements of the Code.
- Monitor the care and use of animals, including housing conditions, practices and procedures involved in the care of animals in facilities.
- Take appropriate actions regarding unexpected adverse events.
- Take appropriate actions regarding non-compliance.
- Approve guidelines for the care and use of animals on behalf of DPIRD.
- Report on its operations to DPIRD and the Scientific Licensing Unit.
- Provide advice and recommendations to DPIRD regarding the care and use of animals for scientific purposes conducted on behalf of DPIRD, and strategies required to ensure that the requirements of the Code are maintained and that matters affecting animal wellbeing are addressed.
- Examine and comment on all DPIRD plans and policies that may affect the welfare of animals used for scientific purposes.
- Perform all other duties as required by the Code.

The Wildlife AEC Executive Officer (EO) shall ensure all records relating to the Wildlife AEC and its workings are maintained in accordance with the Code; and remain available for review by DPIRD and authorised external reviewers. These records will include:

- A register of all applications to the Wildlife AEC, including the outcomes of deliberations.
- Minutes that record decisions and other aspects of the Wildlife AEC's operation.

- Records of inspections conducted by the Wildlife AEC where applicable.
- Management of adverse events and incidents pertaining to the Wildlife AEC.

#### 4. Wildlife AEC membership, appointments, and support

#### 4.1 Membership

DPIRD shall appoint a Chair to the Wildlife AEC who holds a senior position in the Department, or a suitable external appointee, to which DPIRD must provide the necessary support and authority to effectively carry out the role. A Deputy Chair will also be appointed by the Chair.

The Chair shall be an appointment additional to the Category A-D members.

#### 4.1.1 Chairperson

The Chair will:

- Maintain a sound understanding of the Act, the Code, relevant DPIRD policies, procedures, and requirements.
- Ensure the Wildlife AEC, its Executive and Animal Ethics Officers operate in accordance with the spirit and letter of the Act, the Code, DPIRD's licence, DPIRD policies and AEC operating procedures.
- Ensure proposals are considered by the Wildlife AEC and decisions are conveyed to investigators in a timely manner.
- Ensure that the Wildlife AEC's decisions and directives are enacted, with advice being provided to the institutional licensee where individuals or groups do not act on or show due regard for such decisions and directives when effectively communicated.
- Hear, and respect the confidentiality of, any concerns raised regarding the ethical and humane treatment of animals used for scientific purposes.
- Oversee all requirements of the Wildlife AEC to report and review its operations as outlined in the Code.
- Ensure Wildlife AEC records are maintained and made available for review by DPIRD and authorised external reviewers.
- Advise DPIRD regarding the resource needs of the Wildlife AEC.
- Consult with DPIRD, AEC officers and others, as appropriate, in matters relating to the Wildlife AEC's operational effectiveness and the ethical and humane treatment of animals used for scientific purposes.
- Represent the Wildlife AEC in any negotiations with institutional and DPIRD staff and/or management.
- Be responsible for resolving conflicts of interest related to the business of the Wildlife AEC.

#### 4.1.2 Wildlife AEC members

In addition to the Chair, the Wildlife AEC must have a minimum of two members from each of the membership categories. The Director General DPIRD shall appoint at least two members in each of the following Categories to ensure a quorum, consistency in decision-making over members terms, and provide the committee with a broad range of knowledge and experience relating to animal welfare, wildlife research and management, and biological survey.

<u>Category A</u>: 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.

<u>Category B</u>: 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 AEC. This must include possession of a higher degree in research or equivalent experience.

<u>Category C</u>: 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 interest and/or experience in animal welfare 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 organization.

<u>Category D</u>: 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 AEC and must not fit the requirements of any other category.

#### 4.2 Selection, appointment, and obligations

Prospective appointees shall be considered based upon recommendation(s) from the Wildlife AEC members, other relevant AECs or DPIRD. If no suitable candidates are readily available, appropriate advertising will be utilised.

Prospective appointees will submit a resume that shall include a declaration of interest. The Chair will consider any conflicts of interest in determining suitability of the prospect, before the candidate is considered by the full AEC.

Appointments shall be made by the DG or delegate.

Suitable candidates will be offered a letter of appointment in writing which the appointee will sign upon their acceptance.

Prior to commencement, new appointees must acknowledge in writing their acceptance of the Wildlife AEC's TOROPs and confidentiality agreement.

Members of the AEC are covered by DPIRD's insurance whilst engaged in Wildlife AEC business. External members will be offered sitting fees and other expenses if eligible (e.g., travel).

Where appropriate, suitable training such as conferences, seminars or workshops will be made available to members.

DPIRD will ensure that AEC members undergo appropriate induction and have access to appropriate education programs and resources e.g., animal ethics training such as ANZCCART ComPass modules.

#### 4.2.1 Primary/secondary categories of membership

During the initial induction process, AEC members shall be assigned a primary category. Some members may be eligible to fulfil the requirements of a secondary category. Under exceptional circumstances, at the request of the Chair and with the approval of the member, they may act in a secondary category, instead of their primary,

provided they still meet the criteria of the alternate category, the meeting remains quorate and with their vote counted for ONE category only. Category D members cannot change category

#### 4.2.2 Confidentiality

Wildlife AEC members must sign a Deed of Confidentiality prior to appointment. DPIRD staff are bound by confidentiality as a condition of their employment.

The Chair, Executive Officer (EO) and Wildlife AEC category members must maintain confidentiality regarding the membership of the Wildlife AEC, the content of applications and the deliberations of the Wildlife AEC, in accordance with DPIRD requirements.

A declaration of confidentiality is a standing item at Wildlife AEC meetings.

Wildlife AEC members may seek advice from the Chair on any AEC matter. The Chair will respect the confidentiality of any concerns raised and manage complaints in accordance with DPIRD policy and Wildlife AEC TOROPs.

Sharing of departmental information may be processed under the *Freedom of Information Act 1992* in accordance with DPIRD procedures.

#### 4.3 Term and termination

Inaugural members of the Wildlife AEC shall be initially appointed for a one-year term upon acceptance of a written offer. Category A, B, C and D members may be offered additional three-year terms subject to mutual agreement. The Chair's term shall be determined by DPIRD. The need for a turnover of members over time should be considered.

Members may terminate Wildlife AEC membership by formally advising the Chair in writing or during a minuted AEC meeting. The notice of termination shall be no less than 3 months unless approved by the Chair.

If a member is in breach of their obligations, then DPIRD may, after due enquiry and subject to the severity of the breach, issue a verbal reprimand or a written notice of warning or a letter of termination of the membership of a person who, in DPIRD's opinion, has failed to:

- Comply with the Wildlife AEC's Terms of Reference and Operating Procedures.
- Act in a manner to maintain DPIRD's and the Wildlife AEC's positive public image and reputation.
- Maintain the confidentiality required by the Wildlife AEC or DPIRD.
- Without good reason, attend three meetings in succession or at least fifty percent of meetings in each year of appointment.

#### 4.4 Support to the Wildlife AEC

DPIRD will support the effective operation of the Wildlife AEC by appointing an Executive Officer (EO) and services of the Animal Welfare Office when required. Additional staff may be appointed as required to ensure compliance with the Code.

#### 4.5 Wildlife AEC Executive

The Wildlife AEC Executive shall be determined by the AEC members and consist of the Chair and at least one Category C and Category D member. The AEC will nominate

a primary Executive Category C and Category D. If the primary member is unavailable, then the secondary Category C or Category D member will form the Executive. If the Chair is unavailable, the Deputy Chair will fill the role.

#### The Wildlife AEC Executive:

- May approve minor amendments/revisions to approved activities which will be ratified by a quorate AEC at the next available meeting (refer to Appendix 2).
- Shall carry out other functions as delegated by the AEC and in accord with the Code. Such functions may include:
  - Urgent minor matters (refer 5.1).
  - Emergency approval of animal use (refer 6.4).
  - Determine if a proposal requires AEC approval (refer 6.1.1).
  - Decide on matters of non-compliance to determine the severity of a breach, its impact on animals and determine if further action is required. In the case of a serious breach, this function will require the full AEC.
  - Establish terms of reference, where appropriate, for an investigation into a breach/non-compliance (refer 14.4)
- Must not approve applications for new projects or activities, and the ongoing approval for existing projects and activities. This is only permitted at quorate meetings of the AEC.
- Executive decisions must be ratified at the next AEC meeting. If there is disagreement with the Executive decision, then the full AEC should attempt to arrive at a consensus (refer 6.2).

#### 5. AEC meetings

#### 5.1 Ordinary and extraordinary meetings

Ordinary meetings shall be held face-to-face or remotely. AEC members may attend a meeting via electronic means where a face-to-face meeting is not possible.

For urgent and serious matters, the Chair may request an extraordinary meeting of the full AEC. Extraordinary meetings shall be face-to-face where possible. AEC members may, with the Chair's approval, attend an extraordinary meeting via electronic means.

Where deemed appropriate by the Executive Officer and/or Chair, out-of-session items such as amendment / revision requests, may be considered and approved via email and/or teleconference. Such approvals will be endorsed and minuted at the next AEC meeting.

The AEC Executive may consider urgent, minor out-of-session items by way of email or electronic means. Executive decisions will be ratified at the next ordinary AEC meeting.

#### 5.2 Meetings schedule

The WAEC will meet at a frequency sufficient to allow for its effective functioning. Nominally this will be seven scheduled ordinary meetings each calendar year, consisting of six bi-monthly meetings to consider new application proposals and other relevant business (as required), and one annual meeting to consider the Annual Animal Use Reports (AAUR).

If there are no new applications or other relevant business, a scheduled meeting may be cancelled. A schedule of yearly meeting dates will be supplied to the AEC members in advance and placed on the DPIRD Wildlife AEC website.

#### 5.3 Quorum

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.

The AEC must consider and approve applications for new projects and activities, and the ongoing approval for existing projects and activities, and major amendments only at quorate meetings of the AEC.

#### 5.4 Conflict of Interest

During their appointment to the Wildlife AEC, and before any deliberations at an AEC meeting, members must declare any interest that could influence the objectivity of their decision-making.

A request for disclosures of this nature shall be a standing item at all AEC meetings.

The Chair is responsible for resolving conflicts of interest related to the business of the AEC.

Wildlife AEC members and experts, whose advice is sought by the AEC, and who declare a conflict of interest, **must withdraw from the meeting**, and not take part in the AEC's decision-making on matters that relate to the conflict of interest.

This does not preclude a conflicted member or expert from being asked to provide information relevant to the AEC but they must then remove themselves prior to the AEC's deliberations and decision-making.

In the case of the Chair declaring a conflict of interest, the Chair will hand over the meeting to the Deputy Chair or suitable AEC member and remove themselves whilst the AEC deliberates.

The remaining AEC members must still constitute a quorum with Category C and D together representing no less than one-third of the remaining members present.

The conflict of interest and the way it was resolved shall be recorded in the minutes.

#### 6. Review and assessment of new projects

The EO and Chair shall offer appropriate direction and guidance to proponents to assist with determining whether a proposed activity or project requires Wildlife AEC approval. DPIRD's Interim Policy for environmental scientists gives direction on what procedures need to have ethical oversight. <u>Environmental scientists interim policy FAQs</u>

They will also assist in the process of obtaining approval for their proposals or amendments, management, monitoring, evaluation, and reporting of activities involving the scientific use of animals. All reasonable measures should be taken to ensure that the proponent understands their responsibilities, avoiding potential breaches of the Code or Act.

#### 6.1 Assessment and approval

#### 6.1.1 Preliminary assessment

The EO and Chair will undertake a preliminary assessment of applications and other documents received to ensure they are administratively correct and suitable for assessment by the AEC members.

#### 6.1.2 Wildlife AEC assessment of applications

Only a fully quorate AEC may approve applications for new projects and activities, and the ongoing approval for existing projects and activities. The AEC is required to assess proposals submitted for consideration and decide whether approval for the project is granted. The use of animals for scientific purposes must not proceed without prior approval from the AEC.

Consideration will only be given to proposals which:

- Are submitted on a Wildlife AEC approved application form and received by the specified submission date. Late submissions will only be considered under exceptional circumstances and at the discretion of the Chair.
- Have a copy of the institutions or individual's Scientific Use Licence (SUL) attached.
- Are signed by the Chief Investigator (CI) and all other relevant signatories as indicated on the AEC proposal application form (the Chair will sign off after confirmation of the AEC's decision). Proposals without signatures will not be accepted.
- Must use plain English and contain the level, type and clarity of information that the AEC might reasonably expect in order to make informed decisions.
- The AEC has confidence the CI has regard for the welfare of animals and procedural requirements.

Post-graduate students or undergraduates involved in research associated with their studies are not eligible to be the CI of a project. For student projects, the supervising academic may be nominated as the CI, but they must be aware that they will have personal responsibility for all matters that relate to the wellbeing of the animals including their housing, husbandry, and care. This responsibility extends throughout the period of use approved by the AEC until provisions are made for the animal at the conclusion of their use.

Approval will only be granted to proposals that clearly demonstrate:

- The use of live animals is necessary and justified. This includes proposals that
  may not handle animals but use animal material (scats, hair, etc) that were
  trapped specifically for the project by another party.
- The Chief Investigator has appropriately applied the '3R' principles of replacement, reduction, and refinement.
- The proposed care and monitoring arrangements are consistent with the intent and requirements of the Code. Activities that are likely to cause pain or distress must be monitored at an early phase during the conduct of an activity and this shall be a requirement for approval.
- All personnel have the competencies needed to perform all procedures required by the activity.

- The activity does not represent an excessive risk to the welfare of the animals being used.
- Known and potential causes of adverse impact on the wellbeing of animals have been identified, and strategies developed to avoid or minimise harm, including pain and distress.
- The application of scientific rigor.

A pilot study should be incorporated into the design of the project if the potential impact on the animal cannot be predicted based on available evidence.

#### 6.2 Decision-making

Each Wildlife AEC member will be given an opportunity at meetings to provide written or verbal comments on new project applications, amendments, adverse events and other matters before the AEC. Following discussion of these comments, a final decision will be made. The AEC may invite the CI, or any other person to provide further information or advice as it sees appropriate.

Decisions should be made on the basis of consensus. Where consensus cannot be reached after reasonable effort to resolve differences, the AEC should explore with the applicant(s) ways of modifying the project or activity that may lead to consensus.

If consensus is still not achieved, the AEC should only proceed to a majority decision after members have been allowed a period of time to review their positions, followed by further discussion.

All category members have the right to vote, except under circumstances where an AEC member has a conflict of interest.

Each member present at a meeting is entitled to one vote per decision at that meeting. Should there be an equal number of 'for' and 'against' votes, the Chair will provide a casting vote.

#### Wildlife AEC decisions may fall into one of four categories:

- Approved approved with, or without conditions.
- Conditionally approved approval is conditional subject to minor, or major amendment/revision, and review of these by the Chair and/or Executive (minor revision) or full AEC (major revision).
- Not approved the proposal is not approved; another new project application is required.
- Deferred a decision is deferred pending the Wildlife AEC obtaining further information from either the Chief Investigator and/or other sources.

Final AEC approvals must only be given under the signature of the Chair. Work on a project cannot commence until AEC approval has been obtained.

#### 6.3 Duration of approval

Wildlife AEC approval is for a maximum term of three years. The AEC may approve a term in excess of three years under special circumstances that consider the special nature of the research project and anticipated outcomes.

In determining the duration of approval for individual projects, the AEC should consider the number of years for which the project is funded, any milestones or stages outlined in the project, and any formal agreements between the proponent's institution and Wildlife AEC Terms of Reference and Operating Procedures - July 2022 Page 12 of 30 funding bodies. Consideration should also be given to the duration of the SUL held by the institution or individual and the possibility of needing to have that renewed while the approved project is underway.

The duration of activities must be no longer than required to meet the aim(s) of the project and must be compatible with supporting and safeguarding animal wellbeing. Animals must not be held for prolonged periods as part of an approved project before their use, without AEC approval.

#### 6.3.1 Project extension

CIs may apply for an extension beyond the three years of their current project, due to unforeseen circumstances. The AEC shall consider those requests at the next available AEC meeting or, under exceptional circumstances, as an out-of-session request which may be conducted via email and/or teleconference where appropriate.

A project extension of less than three months is considered a minor amendment unless it changes the project's aims or design or increases the risk of harm to animals.

A project extension of three months or more is considered a major amendment and will require full AEC approval (refer to Appendix 2).

The Wildlife AEC may:

- Approve the requested extension with or without conditions.
- Reject the extension application.

If an extension application is rejected, the CI may resubmit as a new application in the normal manner.

# 7. Personnel training, competency, and standard operating procedures.

#### 7.1 Personnel training

Personnel involved in the care and use of animals used for scientific purposes are required to be appropriately trained and competent with the necessary skills and have an understanding of their own responsibilities.

Personnel listed on Wildlife AEC proposal documents, must demonstrate competency, or be prepared to complete any appropriate training required. The ANZCCART ComPass Animal Welfare Training course is highly recommended for all personnel involved, as well as for Wildlife AEC members, and over time may become mandatory.

#### 7.2 Competency of personnel

All personnel involved in the conduct of an approved project must have the appropriate animal handling and care skills and be deemed competent in these. This is the responsibility of the licensee.

The EO will maintain a register of personnel competencies.

Personnel in training must be under the direct supervision of a person competent to perform the procedures.

The CI of each project is ultimately responsible, by way of a signed declaration, for ensuring all personnel involved are deemed competent, as applicable to their assigned role.

#### 7.3 Standard Operating Procedures (SOPs)

The Wildlife AEC shall approve SOPs for project-specific procedures and the general care and husbandry of animals that are held and used for scientific purposes. The Department of Biodiversity, Conservation and Attractions (DBCA) has developed and approved SOPs for several wildlife capture, handling, and processing techniques and these will be available for the Wildlife AEC members and applicants to refer to.

The Wildlife AEC shall encourage SOPs to be developed where a procedure:

- Is not currently adequately covered by an approved SOP.
- May pose a welfare risk to an animal if not carried out appropriately.
- Requires specifically trained personnel.
- Is likely to be repeated in future project proposals.

SOPs cannot be used or referred to in applications or other documents until they have been approved by the AEC. The Wildlife AEC must review approved SOPs every three years or when a change to any part of the SOP is proposed.

#### 8. Notification of Wildlife AEC decisions

The Wildlife AEC, via the EO must clearly communicate its decisions, the reasons for its decisions and any conditions attached to an approval to investigators in writing as promptly as possible.

When communicating the outcome of a proposal application the AEC must advise the CI of the outcome in writing:

- If the proposal is approved without change, the final version of the proposal document as approved by the AEC and signed by the AEC Chair.
- If conditional approval is granted, subject to modifications, the CI will be sent formal notice of the outcome and conditions that must be fulfilled in order for the project to be signed off by the Chair and or the Executive. The CI shall make the required changes and submit the amended proposal to the EO. The final version is then checked and signed by the Chair if satisfied. The CI is advised in writing that the proposal is approved along with the final approved document and any other relevant documents. The CI must be advised of the provisions under the Act to display their Scientific Use Licence.
- If the proposal is rejected, the CI is advised of the outcome and that the activity cannot commence.

The CI may re-submit the proposal if the CI believes the Wildlife AEC's concerns can be satisfied. The proposal will be treated as a new application and must be:

- Amended to address all concerns raised by the AEC.
- Re-signed by all participants as if a new proposal.
- Considered by the full AEC.

#### 9. Amendments to approved projects or activities

No element of an activity may be amended from that as detailed in the AEC approved proposal without an amendment being formally approved.

A request for an amendment to an approved project must be in writing to the EO with the reasons for the amendment and any potential impact on the project and animals must be provided. The current approved application form must be submitted with the proposed amendment clearly highlighted and with tracked changes.

The AEC will only consider amendments that are sufficiently detailed and contain the level, type, and clarity of information which the AEC might reasonably expect to make an informed decision, and which are submitted within a timeframe acceptable to the AEC.

The Chair will determine if an amendment is minor or major (see Appendix 2), and on a case-by-case basis. As a guiding principle, changes to the hypothesis, aims and objectives, or proposed experimental methods or changes that may impact on the wellbeing of the animal(s) are considered major amendments. These need to be assessed and approved by a quorate Wildlife AEC. Minor amendments can be considered by the AEC Executive.

Amendments for noting only will be determined by the AEC Executive. The full AEC will be notified at the next AEC meeting.

Amendment requests to the AEC Executive or full AEC, if the request is urgent, may be managed and approved by way of emails. AEC Executive decisions will be ratified at the next AEC meeting.

Non-urgent requests for amendments will be determined at the next available AEC meeting.

The AEC will accept up to a maximum of three major amendments to an activity. More than three amendments will require re-submission and will be treated as a new proposal. Minor amendments requests will be treated on a case-by-case basis but more than three may be considered at the discretion of the AEC.

#### 10. Monitoring the care and use of animals

Once a wild animal (including a feral and/or introduced species) is encountered or captured as part of an approved project, the CI becomes responsible for ensuring adequate monitoring of its wellbeing while under their control, and that responsibility continues for the duration of the project and until provisions are made for the animal at the conclusion of their use.

The Wildlife AEC must ensure adequate monitoring of all activities relating to the care and use of animals including the acquisition, transport, breeding, housing, husbandry, wellbeing, and disposal of animals as well as the conduct of the activity including the review of procedures, records and reports.

The Wildlife AEC must ensure that identified problems and issues receive appropriate follow up.

Any harm, including pain or distress, must be promptly detected, recorded and appropriately managed. Activities and procedures that may cause pain or distress must be monitored at an early phase during the conduct of the activity.

The AEC application should explain how the CI or delegated personnel will monitor animal welfare and manage impacts including signs of elevated stress, ejected pouch young and unexpected injuries or death. Include details, where appropriate, on the decision-making steps that project personnel will take regarding adverse events. This includes a euthanasia plan which outlines the decision-making process for determining when an animal should be humanely killed, and any arrangements for euthanasia and/or post-mortem examination.

Noting that many of the applications assessed and approved by the Wildlife AEC are likely to be undertaken in remote areas, the AEC shall determine the minimum frequency and timing of inspections depending on factors such as accessibility. If animals are to be held for extended periods in an accessible facility such as a university animal house, regular inspections will be arranged by the AEC. Inspections may be announced or unannounced.

The Wildlife AEC may authorise a suitably qualified delegate (for example, a university Animal Welfare Officer) to carry out site inspections and monitoring of activities on behalf of the AEC.

#### 11. Management of issues / adverse events

Problems and issues that are identified by the CI or delegated personnel must receive appropriate management and follow-up and must be reported to the Wildlife AEC.

Non-compliance with the Code or approved conditions must be dealt with as per AEC TOROPs (refer to section 15).

#### 11.1 Unexpected Adverse Event Report (AER)

The Code requires that institutions must ensure CIs and those responsible for the care and monitoring of animals are aware of their obligation to provide prompt notification of any unexpected adverse event(s) to the AEC. The CI must submit an adverse event form to the Wildlife AEC EO within 24 hours of discovery.

The CI must also take appropriate action(s) to ensure animal wellbeing is not compromised, the issue is addressed promptly and activities that have the potential to adversely affect animal wellbeing cease immediately. Actions required for unexpected adverse events and emergencies, must include 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. This 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 (clause 2.1.5).

The AEC may, where necessary, suspend or withdraw approval for the project or activity (The Code, clause 2.3.24)

#### 11.2 Summary reports and the management of incidents

- The EO shall compile summary reports on deaths, adverse incidents, annual usage, and activity completions grouped according to their level of significance and submit the compiled reports to the AEC with recommendations on both the level of scrutiny required and proposed actions.
- The EO, with the support of the AWO, shall use all reasonable efforts to identify any issue or report which may be considered to raise critical issues and bring

- them immediately to the attention of the AEC Chair. These may then be communicated to the AEC as an 'AEC Alert Notification' due to perceived significant welfare risks and/or possible breaches of procedures.
- The EO shall provide appropriate directives to the CI regarding the AEC decisions; where possible monitor compliance with those directives, and promptly report any identified anomalies to the Wildlife AEC Chair for appropriate action.

#### The Wildlife AEC shall:

- Consider any issue or report which may, in the opinion of the Chair, represent a
  critical risk to the ethical or humane treatment of animals, government or
  industry, by way of a special meeting as agreed with the Chair.
- Consider summary reports on all other death, adverse incidents, annual usage, and activity completion reports at its earliest scheduled meeting.

### 12. Standard reporting of activities by the CI to the Wildlife AEC

#### 12.1 Project Completion Report (PCR)

A PCR must be submitted to the EO within six weeks upon completion of a project. The Wildlife AEC will not consider any new applications from the CI until the PCR is received.

The EO and Chair must review PCRs to confirm that animal use is consistent with and in accordance with the approved application for the activity.

The PCR must contain sufficient detail to demonstrate if project outcomes were achieved and what might be improved in future projects.

The final PCR is provided to the Wildlife AEC for consideration at the next AEC meeting.

#### 12.2 Annual Animal Use Review (AAUR)

All approved projects and activities are subject to an annual review.

The EO and Chair will provide appropriate guidance to the CI regarding the development and submission of the Animal Use Report. The report must contain sufficient detail to allow the AEC to make a proper determination.

The AEC will consider the AAUR at a meeting early in the calendar year, with particular regard to:

- confirming that animal use remains necessary and justified.
- care and management remain consistent with the intent and requirements of the Code.
- the AEC retains confidence in the proponent's regard for the welfare of animals and related procedural requirements.
- the activity complies with AEC approval and the requirements of the Code.

At the AAUR meeting, the AEC will determine whether the activity may continue, be modified, suspended or discontinued. The AEC may require further information before a decision is made. The EO will notify the CI of the AEC's decision.

#### 12.3 Other reports

The Wildlife AEC may require any other additional reports as a condition of approval or during the project.

## 13. Complaints and non-compliance relating to the care and use of animals for scientific purposes

Complaints may arise concerning:

- The care and use of animals by institutions.
- The AEC process of review and decision-making.
- The process for Independent external review.

#### 13.1 Complaints concerning the care and use of animals by institutions

- Complaints may also involve non-compliance (refer to section 14.4).
- Priority consideration must be given to the wellbeing of the animals. Activities
  that have the potential to adversely affect animal wellbeing must cease
  immediately.
- Where complaints relate to activities that would normally require AEC approval, the complaints are referred to the AEC to investigate whether such activities are conducted in accordance with AEC approval.
- Where a complaint arises from a member of the public, the complaint will be considered by the AEC Chair and a formal response issued. If the Chair's formal response is not accepted, then the complaint will be submitted to the DPIRD Director General or delegate for consideration.
- Where complaints raise the possibility of 'research misconduct', as described in the <u>Australian Code for the responsible conduct of research</u>, the complaint is handled in accordance with procedures specified in that document.
- Where complaints allege misconduct that falls outside the range of 'research misconduct', the complaint is handled in accordance with DPIRD processes for dealing with other forms of misconduct (refer <u>DPIRD Discipline & Misconduct</u> <u>Procedure - 2018</u>).

At the discretion of the Chair and/or as directed by the Wildlife AEC, an investigation can be undertaken into the complaint by an independently appointed person. Where appropriate, terms of reference will be established by the Wildlife AEC or AEC Executive for the case at hand.

The investigation must ensure fair, prompt, timely, effective, confidential processes that accord with procedural fairness, the principles of natural justice and protection of whistle-blowers.

Following the Wildlife AEC's investigation of complaints, the AEC must:

• Ensure that, where complaints relate to activities that would normally require AEC approval, the activities are reviewed in consultation with all relevant people to ensure that the reason for the complaint is addressed. The AEC may decide

- that modification to a project or activity is required, or an approval for a project or activity is suspended or withdrawn.
- Ensure appropriate reporting to the CI, Licensee and other relevant bodies or institutions.
- Where activities are not conducted in accordance with legislative requirements including AEC approval, the matter will be dealt with as a non-compliance (section 14.4).

#### 13.2 Complaints concerning the Wildlife AEC process

If a CI is aggrieved by a decision of the AEC, the Chair on behalf of the AEC will offer the CI an opportunity to submit the grievance in writing and/or address the AEC at its next meeting. If the CI remains aggrieved, they may appeal the matter in writing to the Director General or delegate. In which case the DG or delegate:

- Shall, in the first instance, refer the matter to the Wildlife AEC Chair for comment.
- May convene a panel comprising at least the DG or delegate, AEC Chair and one external member of the AEC, with the applicant being able to make a submission to the panel.

The DG or delegate (or panel, if convened) will make a recommendation to the AEC.

Following this review, the AEC 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 AEC and must not be overridden by DPIRD.

Where a grievance arises between AEC members or between AEC members and institutional staff, the grievance resolution process available to DPIRD staff will be extended to external members of the AEC to achieve a resolution (refer <u>DPIRD</u> <u>Grievance Management Policy & Procedure - 2018</u>).

#### 13.3 Complaints concerning the process for independent external review

DPIRD must ensure that the process for conducting an independent external review, developed in consultation with the review panel, includes an appeals process that relates to the process and outcomes of the review.

#### 13.4 Non-compliance

Non-compliance with the Code or the Act may involve any party or person involved in the care and use of animals including investigators, animal carers, the AEC, governance officials, and external parties subject to formal agreements.

Non-compliance may be identified through a complaint, AEC monitoring or self-disclosure.

Non-compliance may vary in degree of seriousness from a minor breach of the Code, or conditions of AEC approval, to a major breach of the Act. Action taken should be in proportion to the breach and its context.

Management of non-compliance:

- Priority actions must be 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 must cease immediately.
- The CI or animal carer must ensure prompt notification to the EO. The EO must notify the AEC Chair as soon as possible. The Chair will determine to notify the AEC Executive (or full AEC).
- Actions must be taken to address the issues in consultation with the CI or other person(s) involved.
- At the direction of the AEC or its Executive, an investigation will be undertaken into a matter by the EO or another suitable person. Where appropriate, terms of reference will be established by the AEC or its Executive for the case at hand.
- The investigation must ensure fair, prompt, timely, effective, confidential
  processes that accord with procedural fairness, the principles of natural
  justice and protection of whistle-blowers. The CI must be notified in writing as
  soon as practicable.
- AEC disciplinary actions should be in proportion to the breach and its context.
   Actions may include a written warning, or suspension or withdrawal of approval for a project or activity (clause 2.3.25, 2.3.9). The AEC may also reconsider other approvals granted to the same CI and/or may refuse to receive applications from a CI for a period.
- The relevant institution/licensee shall be notified in writing of all cases of non-compliance.
- Major or serious non-compliance matters may be referred to the DG or delegate for action in accordance with DPIRD policy and procedures. The AEC shall provide written advice to DPIRD as soon as practicable and may include recommendations to DPIRD. Recommendations may include referral to the Scientific Inspector for action under the Animal Welfare Act.
- DPIRD must ensure and support the effective operation of the AEC by addressing concerns raised by the AEC regarding non-compliance that may include disciplinary action upon the advice of the AEC (clause 2.1.6)
- DPIRD shall advise the regulatory authorities in writing of alleged breaches of legislation that had a significant impact on animal wellbeing or in regards to other serious breaches upon the advice of the AEC.
- Non-compliance must receive appropriate follow-up.
- The Ethics Office must maintain records of non-compliance.
- DPIRD must conduct an annual review of its non-compliance processes (*clause 2.1.9*).

#### 14. Annual reports and independent external reviews

#### 14.1 Annual report

The Wildlife AEC shall provide an annual report on its activities, including a statement indicating compliance with the Code, to the DPIRD DG and to any other licensed scientific establishment that uses DPIRD's Wildlife AEC.

The Wildlife AEC annual report shall also form part of the submission to the Scientific Licensing Unit to comply with licence requirements.

The report shall include:

- Numbers and types of projects and activities assessed and approved or rejected.
- The physical facilities for the care and use of animals by any of the institutions receiving Wildlife AEC approval.
- Activities that have supported the educational needs of the AEC members, and of personnel involved in the care and use of animals.
- Administrative or other difficulties being experienced.
- Any matters that may affect DPIRD's ability to maintain compliance with the Code and if necessary, the provision of suitable recommendations.
- Set intervention points and experimental humane endpoints.
- Approvals involving 'death as an endpoint.
- Euthanasia and/or humane killing protocols or SOPs.
- Any other matters required for the annual animal use report.

#### 14.2 Independent external review

The Wildlife AEC is subject to an independent external review of its processes and operation at least every four years to assess its' compliance with the Code, and to ensure the continued suitability, adequacy and effectiveness of its procedures to meet its responsibilities under the Code.

The purpose of the external review is to provide assurance to DPIRD, that there is effective oversight of the care and use of the animals being used by non-government institutions and environmental scientists in WA.

The independent external review includes:

- The conduct of all personnel involved in the care and use of animals for scientific purposes on behalf of non-government institutions, including the Wildlife AEC, staff, investigators, and animal carers.
- Smaller organisations in WA that use another Institution's established AEC (such as environmental scientists or private consultants) may not have the capacity to undertake an external review of their own. Therefore, it is possible for such institutions to consider arranging for their animal use to be covered by the nominated AEC's external review, i.e., via Wildlife AEC. Given that the external review is a licence condition, it is the licensee's responsibility to ensure that the review is conducted in accordance with the Code and that any such arrangements are confirmed to the SLU in writing by their nominated ER panel.
- The adequacy of non-government institution programs to ensure that the care and use of animals for scientific purposes is conducted in compliance with the

- Code; is subject to ethical review, approval and monitoring by an AEC; and is conducted in accordance with the AEC approval.
- The adequacy of DPIRD support, resources and educational programs for the AEC and its members, and for people involved in any aspect of the care and use of animals for scientific purposes, to ensure that they can meet their responsibilities under the Code.
- Whether the AEC is operating effectively in accordance with the Code.
- The effectiveness of DPIRD strategies to promote and monitor the implementation of the governing principles.
- Whether there is effective monitoring of the wellbeing of animals.
- Whether facilities used to house animals are managed to support and safeguard animal wellbeing.
- If applicable, an assessment of the report from the previous external review and actions taken in response to recommendations in that report.

The review panel shall provide recommendations that:

- Identify areas of non-compliance.
- Support strategies for short-term and long-term continual improvement.
- Give recognition to behaviours and actions by individuals and teams that support compliance.

As a condition on DPIRD's licence, the Wildlife AEC must provide a response to the review panel's final report to DPIRD's licensee.

DPIRD's licensee must provide to the DG of the Department within 120 days of the end of the review period, the final review report, the AEC's response, the licensee's response to the final review report and the licensee's response to the AEC's response.

DPIRD and its Wildlife AEC shall ensure all accepted recommendations are addressed as soon as possible.

If the review panel fails to adequately demonstrate compliance with DPIRD's licence conditions or identifies areas of non-compliance with the Code, the Regulator may investigate the licensee's use of animals for scientific purposes in WA.

#### **Appendix 1**

#### **Glossary**

Adverse event: any event that has a negative impact on the wellbeing of an animal.

 Unexpected adverse event: an event that may have a negative impact on the wellbeing of animals and was not foreshadowed in the approved project or activity.

An unexpected adverse event may result from different causes including but not limited to:

- death of an animal, or group of animals, that was not expected (e.g. during surgery or anaesthesia, or after a procedure or treatment)
- o adverse effects 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 or activity, based on the number of animals used, not the number approved for the study
- a greater level of pain or distress than was predicted during the planning of the project or activity
- power failures, inclement weather, emergency situations, or other factors external to the project or activity that have a negative impact on the welfare of the animals.

The AEC must 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 or activity.

**AEC Executive:** must include the Chair and at least one member from Cat C and D. May approve minor amendments to approved projects or activities, for ratification at the next AEC meeting. The AEC may delegate other functions to the AEC Executive.

**Animal:** any live non-human vertebrate (that is, fish, amphibians, reptiles, birds, and mammals encompassing domestic animals, purpose-bred animals, livestock, wildlife) and cephalopods. (Cephalopods are marine molluscs e.g. squid, cuttlefish, and octopuses).

**Animal Ethics Office (Ethics Office):** Wildlife AEC Executive Officer, AWO, AWM and the AEC Chair.

**Annual review:** DPIRD must conduct an annual review of the operation of the Wildlife AEC to ensure that it is effective, ensures compliance with the Code, and is consistent with DPIRD policies. The annual review must include the effectiveness of Wildlife AEC processes regarding complaints and non-compliance.

This review must include an assessment of the AEC's annual report and a meeting with the AEC chairperson.

The AEC must submit a written report on its operations at least annually to DPIRD.

The report should advise on:

numbers and types of projects and activities assessed, and approved or rejected

- the physical facilities for the care and use of animals by the institution
- actions that have supported the educational and training needs of AEC members and people involved in the care and use of animals
- 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.

(Clauses 2.1.9, 2.2.1 [v], 2.2.37 and 2.3.28–29)

**Competency:** the capability to apply or use the set of related knowledge, skills, and abilities required to successfully perform 'critical work functions' or tasks in a defined work setting. Competencies often serve as the basis for skill standards that specify the level of knowledge, skills, and abilities required for success in the workplace as well as potential measurement criteria for assessing competency attainment. Competence is a measure of both proven skills and proven knowledge.

**Evidence of competency:** demonstrated and verified ability to perform specified duties based on knowledge, training and experience.

Animal welfare monitoring audits also assess operator competency.

#### **Compliance with the Code:**

- Is referred to in the Act and
- Is a condition of all licences to use animals.
- **Must** is an **obligatory** component of the Code (legal requirement).
- Should indicates a strongly recommended component of the Code (not a legal requirement).

**Conflict of interest:** a situation in which a person's individual interests or responsibilities have the potential to influence the carrying out of his or her institutional role or professional obligations, or where an institution's interests or responsibilities have the potential to influence the carrying out of its obligations.

**Critical limit:** a critical intervention point where a maximum or minimum value such as the number of animals or other parameters which, when met/exceeded, requires immediate action to prevent, eliminate or reduce further risk to animal welfare. The AEC must be notified as soon as possible and may determine further action as required.

**DPIRD Director General (DG):** heads DPIRD, and is also the CEO of the Department in relation to the Scientific Use Licence.

**DPIRD Licensee (licence holder):** the Licensed Scientific Establishment holds the licence. Responsibilities (Table 1).

**Formal agreement:** when an institution uses an AEC that has been established by another institution (DPIRD), such use must be based on a formal agreement that has been developed in consultation with the AEC.

When an investigator who does not have direct access to an institutional AEC uses an AEC established by an institution (DPIRD), such use must be based on a formal agreement that has been developed in consultation with the AEC.

**Independent external review:** DPIRD must regularly monitor and review institutional compliance with the Code by ensuring that an independent external review is conducted at least every four years to assess the institution's compliance with the Code, and to ensure the continued suitability, adequacy and effectiveness of its procedures to meet its responsibilities under the Code (clause 2.1.9).

**Investigator:** any person who uses animals for scientific purposes. Includes researchers, teachers, undergraduate and postgraduate students involved in research projects, and people involved in product testing, environmental testing, production of biological products and wildlife surveys. The **Chief Investigator (CI)** cannot be an undergraduate or postgraduate student.

#### Meetings:

- Ordinary meeting: regular, scheduled Wildlife AEC meetings.
- Extraordinary meeting: a meeting that is outside the regular meeting timetable.
  It is usually called to discuss something important or unusual that requires full
  AEC consideration/approval and cannot be delayed to the next scheduled
  meeting.
- Out of session items: items that arise outside of ordinary meetings and may include urgent amendment requests, unexpected adverse events/incidents, breaches of critical limits and issues of non-compliance. Such items may be dealt with at an extraordinary meeting or by the Wildlife AEC Executive.

**Monitoring:** measures undertaken to assess, or to ensure the assessment of, the wellbeing of animals in accordance with the Code. Monitoring occurs at different levels (including those of investigators, animal carers and animal ethics committees). All activities, including projects, that involve the care and use of animals for scientific purposes must be subject to ethical review, approval, and monitoring by an AEC.

**Necropsy (post-mortem examination):** when an animal dies unexpectedly or is humanely killed due to unforeseen complications, a necropsy should be performed by a competent person (clause 2.1.5[d], 2.5.17[iii], 3.1.25)

**Non-compliance:** non-compliance with the Code by any party or person involved in the care and use of animals including investigators, animal carers, the AEC, governance officials, and external parties subject to formal agreements. Non-compliance may also involve breaches of relevant state legislation.

**Pilot study:** If the potential impact on the animal, or the validity and efficacy of criteria for intervention to minimise harm, including pain and distress, cannot be predicted based on available evidence, the incorporation of a pilot study into the design of the project must be considered to allow staged assessment of the impact on animal wellbeing and the development of strategies to avoid or minimise any adverse impact.

**Regulator / Scientific Licensing Unit (SLU):** administers and enforces Part 2 of the Act, specifically activities done under a licence. The Scientific Inspector makes a recommendation to the Minister on whether a licence should be renewed, amended, revoked or suspended.

#### **Scientific Inspector:**

Conduct site visits

- Observe AEC meetings
- Evaluate Annual Animal Use Reports
- Assess Independent External Review submissions
- Investigate animal use for scientific purposes when indicated.

**Research Facility (RF) manager:** person responsible for the overall management of a facility used for the breeding and holding of animals.

#### Scientific establishment:

- The Act defines a **scientific establishment** as a person who uses, or whose staff or students use, animals for scientific purposes.
- The Code describes an **institution** as any organisation or agency involved in the care and use of animals for scientific purposes.

**Scientific purposes:** all activities conducted to acquire, develop or demonstrate knowledge or techniques in all areas of science, including teaching, field trials, environmental studies, research (including the creation and breeding of a new animal line where the impact on animal wellbeing is unknown or uncertain), diagnosis, product testing and the production of biological products.

**Staff:** in relation to a person, includes;

- All the people working for, or engaged by, that person whether as officers, employees, agents, contractors, volunteers or in any other capacity;
- If the person is a scientific establishment, all the people who use the establishment's facilities for scientific purposes;
- If the person is a body corporate, its directors, secretary and executive officers;
- If the person is in a partnership, the partners.

**Standard Operating Procedure (SOP):** detailed description of a standardised procedure or process. Appropriate use of SOPs as part of the animal ethics approval process may facilitate the preparation of applications by researchers.

- The SOP must have current approval from the AEC.
- The SOP must include in its title the date of approval or last review by the AEC.
- Investigators named in the application must be competent to implement the SOP.
- Any variation to a SOP must be described in the application and should be considered as a prompt for review of the SOP.

**Teaching activity:** any action or group of actions undertaken to achieve a scientific purpose, where the scientific purpose is imparting or demonstrating knowledge or techniques to achieve an educational outcome in science, as specified in the relevant curriculum or competency requirements.

**Three Rs:** the use of animals must be justified, support the animals' wellbeing, avoid or minimise harm and incorporate the principles of **Replacement**, **Reduction** and **Refinement**.

 Replacement alternatives: methods that permit a given purpose of an activity or project to be achieved without the use of animals.

- Reduction alternatives: methods for obtaining comparable levels of information from the use of fewer animals in scientific procedures or for obtaining more information from the same number of animals.
- Refinement alternatives: methods that alleviate or minimise potential pain and distress and enhance animal wellbeing.

#### **Appendix 2**

#### **Major vs minor amendments - Guidelines**

**Background:** At times approved projects require changes to accommodate various situations including changes in staff, changes to methods used and measurements taken, or unexpected welfare risks. To allow for greater consistency and efficiency, the following describes broadly what situations constitute an amendment and therefore requires WAEC, WAEC Executive and/or Chair to approve. All requests will be considered on a case-by-case basis. Up to <a href="mailto:three-Major amendments">three Major amendments</a> may be permitted for a project. If additional major amendments are sought, a new project application may be required.

**Reference:** The Scientific Code (2013) sections: 2.23(ii), 2.4.4(iii), 2.4.10, 2.5.15(i), 2.7.6

| Amendment <b>type</b>  | Definition (Not exhaustive)   | WAEC Process   |
|--|---|--|
| MAJOR Amendment (WAEC approval) Up to 3 permitted over life of project | Any change to the project's aims/objectives.  A significant change to methodology / experimental design / additional invasive procedures.  Increased risk of harm to animals, including pain & distress.  Changes of Chief Investigator (unless Deputy CI).  Project extension > 3 months.  Change in number of animals < 10% from original approval. | CI must provide explanation and justification for the amendment including potential impact on both animal welfare and the project and submit to the Executive Officer for determination by Chair or Deputy Chair.  CI must provide highlighted or track changes sections on the approved New Project Application form showing all proposed changes.  To be considered at the next scheduled WAEC meeting unless exceptional circumstances and deemed urgent, in which case the Executive Officer will convene a virtual meeting (email or teleconference) of a quorate |
|  |   | AEC as soon as possible (this does not have to be face-to-face s.2.2.26 the Code).   |
| MINOR Amendment (WAEC Executive  | A minor change to methodology / experimental design / additional procedures.  | Cl must provide explanation<br>and justification for the<br>amendment including potential<br>impact on both animal welfare   |
| approval)  | Not likely to cause harm to animals, including pain and distress.  Project extension < 3 months.  | and the project and submit to<br>the Executive Officer for<br>determination by the Chair or<br>Deputy Chair  |

| Amendment type  | Definition (Not exhaustive)   | WAEC Process   |
|---|---|--|
|   | Change in number of animals < 10% from original approval.   | CI must provide highlighted or track changes sections on the approved New Project Application form showing all proposed changes.  To be considered at the next scheduled WAEC meeting unless deemed urgent, in which case the Executive Officer will contact the WAEC Executive to discuss/approve out of session either via email or teleconference. The decision will then be ratified at the next WAEC meeting. |
| Amendment for noting (Zero amendment) (Chair / Deputy Chair approval) | No change to methodology / experimental design.  No welfare risk is indicated.  Additional co-worker(s) undertaking approved project procedures such as trapping, spotlighting, observation and routine animal husbandry tasks with competencies provided.  A delay of up to 3 months to the start date with the end date extended by the same amount.  Use of different sex or age animals or change of location where there is no impact on animal welfare and the project. | CI must provide explanation and justification for the amendment and submit to the Executive Officer for determination by the Chair or Deputy Chair.  The Executive Officer to add to the next meeting agenda for noting.   |

# Important disclaimer The Chief Executive Officer of the Department of Primary Industries and Regional Development and the State of Western Australia accept no liability whatsoever by reason of negligence or otherwise arising from the use or release of this information or any part of it. Copyright © State of Western Australia (Department of Primary Industries and Regional Development), 2022