



Department of
Primary Industries and
Regional Development

Protect
Grow
Innovate

Wildlife Animal Ethics Committee - Operating Procedures

November 2025

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1. Review and assessment of new projects

Projects will usually only be considered from environmental scientists who do not have access to an institutional AEC, and which relate to wildlife studies. Applications may be assessed on a case-by-case basis from institutions / Chief Investigators who have access to another AEC but make an adequate case for the need for additional AEC oversight. Student projects from tertiary institutions will not normally be assessed as they should have access to their institution's AEC. Institutions need to have a signed Formal Agreement and a current Scientific Use Licence before submitting applications to the Wildlife Animal Ethics Committee (WAEC).

The Executive Officer (EO) and Chair will offer appropriate direction and guidance to proponents to assist with determining whether a proposed activity or project is eligible and requires WAEC approval. DPIRD's *Scientific Use Licences for environmental scientists in Western Australia – Interim Policy and frequently asked questions* (April 2021) provide direction on what uses of animals require a Scientific Use Licence and need to have ethical oversight. The EO and Chair will also assist Chief Investigators (CIs) in the process of obtaining approval for their proposals or amendments, management, monitoring, evaluation, and reporting of activities involving the scientific use of animals. It is anticipated that an Animal Welfare Officer (AWO) will be appointed to the WAEC in the future and they will also have a role in reviewing projects. All reasonable measures should be taken to ensure that the proponent understands their responsibilities, avoiding potential breaches of the *Australian Code for the care and use of animals for scientific purposes* 2013 (updated 2021) (the Code) or the *WA Animal Welfare Act 2002* (the Act).

1.1 Assessment and approval

1.1.1 Preliminary assessment

The EO and Chair will undertake a preliminary assessment of applications and other documents received to ensure they are administratively complete and suitable for assessment by the WAEC members. Welfare considerations will also be assessed to some extent prior to consideration by the WAEC. The AWO will assist in this aspect once appointed.

1.1.2 Member attendance

WAEC members are expected to attend ordinary meetings when required to ensure the meetings are quorate. Meetings will aim to have a maximum of two members present, however only one member from each category is required for the meeting to be quorate. Where an increased frequency of ordinary meetings is required, members will be rostered to attend so that a minimum of one and maximum of two members are present (participating members). Members not rostered need not attend the meeting unless there are late changes to members availability and they are requested to attend at short notice.

1.1.3 WAEC assessment of applications

All documents that require review by the WAEC will be placed electronically in a secure DPIRD Share Point site a week before the scheduled meeting. Participating members are expected to access and review the documents prior to the meeting. Assessment of applications will be undertaken regularly at either face-to-face meetings or meetings via electronic means such as MS Teams. Only a fully quorate WAEC (at least one member present from each of the Category's A, B, C and D) may approve applications for new projects and activities. The WAEC 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 WAEC.

Consideration will only be given to proposals from institutions/Chief Investigators which:

- Are submitted on the most recent version of the WAEC New Project Application (NPA) 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 signed Formal Agreement (FA) with the WAEC
- Provide a valid Scientific Use Licence (SUL) number.
- Are signed by the Chief Investigator (CI) as indicated on the NPA form.
- Proposals without signatures will not be accepted.
- Use plain English and contain the level, type and clarity of information that the WAEC might reasonably expect to make informed decisions.
- The WAEC has confidence the CI has regard for the welfare of animals and procedural requirements.

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 captured/handled specifically for the project by another party.
- The CI has appropriately considered and 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 demonstrates 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.

1.2 Decision-making

Each participating 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 WAEC. Following discussion of these comments, a final decision will be made. The WAEC may invite the CI, or any other person to provide further information or advice as it sees appropriate.

Decisions will be made based on consensus among the participating members. Where consensus cannot be reached after reasonable effort to resolve differences, the WAEC 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 WAEC 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 WAEC member has a conflict of interest.

Each participating member 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.

All decisions will be recorded in the meeting minutes.

WAEC decisions may fall into one of four categories:

- **Approved** - approved with, or without minor clarifications, and with or without conditions specific to the project.
- **Provisionally approved** - approval is provisional on satisfactory changes or revisions being made by the CI, and review of these by the Chair (minor revision), Executive (moderate revision) or full WAEC (major revision). Review and endorsement of revised provisionally approved projects can be undertaken using email correspondence.
- **Deferred** – a decision is deferred because of inadequate information being provided and further information from either the Chief Investigator and/or other sources is required.
- **Not approved** - the proposal is not approved; another new project application is required.

Final WAEC approval with a permit number must only be given under the signature of the Chair. Work on a project cannot commence until WAEC approval has been obtained.

1.3 Duration of approval

The WAEC can approve projects for up to four (4) years duration. In determining the duration of approval for individual projects, the WAEC 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 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 WAEC approval.

1.3.1 Project extension

CIs may apply for an extension beyond the four years of their approved project of up to 12 months using the project amendment process. The WAEC shall consider those requests at the next available WAEC 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 three months or less is considered a minor amendment unless it changes the project's aims or design or increases the risk of harm to animals. Minor amendments can be approved by the Executive.

A project extension of three months to 12 months is considered a major amendment and will require full WAEC approval (refer to Appendix 2).

The WAEC may:

- Approve the requested extension with or without conditions.
- Seek further justification for the extension
- Reject the extension application.
- If an extension application is rejected, the CI may resubmit as a new application in the normal manner.

2. Training, competency, and standard operating procedures

2.1 WAEC member training

WAEC members are expected to have either successfully undertaken the ANZCCART ComPass online basic animal welfare training course, or able to obtain it within 12 months of joining the WAEC.

WAEC members will also be encouraged to participate in other training opportunities as they arise.

2.2 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 understand their own responsibilities.

Personnel listed on WAEC project application documents, must demonstrate competency, or be prepared to complete any appropriate training required. The ANZCCART ComPass basic animal welfare course is highly recommended for all personnel involved, and over time may become mandatory for CIs and animal handlers.

2.3 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.

2.4 Standard Operating Procedures (SOPs)

The Department of Biodiversity, Conservation and Attractions (DBCA) has developed and approved SOPs for several wildlife capture, handling, and processing techniques and these are approved by the WAEC for use in wildlife studies.

The WAEC can accept the use of other institutions SOPs for procedures not covered by the DBCA SOPs. However, SOPs cannot be used or referred to in applications or other documents until they have been approved by the WAEC. Any SOPs used and referred to in WAEC new project applications must be reviewed by the relevant institution and approved at least every three years to remain valid.

The WAEC will prepare SOPs or encourage other institutions to prepare SOPs where a procedure:

- Is not currently 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.

3. Notification of WAEC decisions

The WAEC, via the EO must clearly communicate its decisions, the reasons for its decisions, any additional information required, and any conditions attached to an approval to investigators in writing as soon as possible after the decision has been made.

When communicating the outcome of a new project application the WAEC must advise the CI of the outcome in writing:

- If the proposal is approved without change, or with minor change, the final version of the new project application becomes the approved protocol, and a permit number is issued. The CI must be advised of the provisions under the Act to display their Scientific Use Licence.
- If provisional approval is granted, subject to modifications, the CI will be sent formal notice of the revisions that must be undertaken 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. If the amended proposal is satisfactory, it can be approved by the Chair or Executive (a few, minor changes) or the WAEC (several, major changes). The CI is advised in writing that the proposal is approved, and a permit number is issued.
- If the project assessment is deferred because of the lack of suitable information, the CI is advised and requested to amend the application accordingly.
- If the proposal is not approved, 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 WAEC's concerns can be satisfied. The proposal will be treated as a new application and must be:
 1. Amended to address all concerns raised by the WAEC.
 2. Re-signed by the CI as if a new proposal.
 3. Considered by the full WAEC.

4. Amendments to approved projects or activities

No element of an activity may be amended from that as detailed in the WAEC approved new project application without an amendment being formally approved.

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

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

The Chair will determine on a case-by-case basis if an amendment is for noting (zero amendment), a minor, or major amendment (see Appendix 2). The Executive's assistance with this may be required. 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 WAEC. Minor amendments can be considered by the WAEC Executive. Zero amendments for noting only will be determined by the Chair. The WAEC will be notified about zero and minor amendment approvals at the next WAEC meeting.

Urgent amendment requests to the WAEC Executive or full WAEC, may be managed and approved by way of emails. WAEC Executive decisions will be ratified at the next WAEC meeting. Non-urgent requests for amendments will be determined at the next available WAEC meeting.

Up to three changes will be permitted for each amendment request. Additional changes will require further amendment requests. The WAEC will accept up to a maximum of four major amendments to an activity. More than four major amendments will require submission of another application and will be treated as a new proposal. The allowable number of minor amendments requests will be treated on a case-by-case basis at the discretion of the WAEC.

5. Monitoring the care and use of animals

Once a wild animal (including 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 WAEC 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 annual progress reports.

The WAEC 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 WAEC new project application should explain how the CI or delegated personnel will monitor animal welfare and manage impacts including signs of elevated stress, 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 WAEC are likely to be undertaken in remote areas, the WAEC shall determine the minimum frequency and timing of monitoring inspections depending on factors such as project risk and 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 WAEC. Inspections may be announced or unannounced.

The WAEC may authorise a suitably qualified delegate (for example, a contractor experienced in animal trapping and handling procedures, and animal welfare issues) to carry out site inspections and monitoring of activities on behalf of the WAEC.

6. Management of issues / adverse events

Project issues, adverse events and any other problems that are identified by the CI or delegated personnel must receive appropriate management and follow-up and must be reported to the WAEC.

Non-compliance with the Code or approved conditions must be dealt with as per Section 8.4 below.

6.1 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. Given the lack of rigorous information about what expected rates of adverse events might be in wildlife studies, the WAEC requires that all adverse events (expected and unexpected) be reported. The CI must notify the WAEC EO via email or phone of an adverse event within 24 hours of discovery and submit an adverse event form as soon as possible after notification.

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 adverse events and emergencies, must include those that require welfare interventions such as the closure of traps, 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 WAEC, 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.

The WAEC may, where necessary, suspend or withdraw approval for the project or activity.

6.2 Summary reports and the management of incidents

The EO shall compile summary reports on deaths and other adverse incidents, annual usage, and activity completions, grouped according to their level of significance, and submit the compiled reports to the WAEC with recommendations on both the level of scrutiny required and proposed actions.

The EO 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 WAEC Chair. These may then be communicated to the WAEC as a 'WAEC 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 WAEC decisions, where possible monitor compliance with those directives and promptly report any identified anomalies to the WAEC Chair for appropriate action.

The WAEC 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. The WAEC will also consider summary reports on all other death, adverse incidents, annual usage, and activity completion reports at its earliest scheduled meeting.

7. Standard reporting of activities by the CI to the WAEC

7.1 – Annual Progress Report (APR)

An Annual Progress Report (APR) is required each year on the anniversary of the project approval date, as outlined in the WAEC Approval Letter. Sufficient detail must be provided on progress against project aims, amendments and adverse events for the WAEC to make an informed decision on project continuation.

7.2 Project Completion Report (PCR)

A Project Completion Report (PCR) must be submitted to the EO within six weeks of completion of a project. The WAEC 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 WAEC for consideration at the next WAEC meeting.

Projects that have come to the end of their approved term (maximum of four years or five years with an approved one-year extension) but are continuing are required to submit a PCR and another new project application form for the project to continue.

7.3 Annual Animal Use Review (AAUR)

All approved projects and activities are subject to providing an Annual Animal Use Review to the **DPIRD Scientific Licencing Unit (SLU)** (*not the WAEC*). The SLU will provide appropriate guidance to the CI regarding the development and submission of Part A of the AAUR. Once this has been accepted the SLU notify the stakeholder and recommend that they send a copy to the WAEC.

The WAEC may review the AAUR reports made available to them and consider if:

- animal use remains necessary and justified.
- care and management remain consistent with the intent and requirements of the Code.
- the WAEC retains confidence in the proponent's regard for the welfare of animals and related procedural requirements.
- the activity complies with WAEC approval and the requirements of the Code.
- the activity should continue, be modified, suspended or discontinued.
- The WAEC may require further information before a decision is made. The EO will notify the CI of the WAEC's decision.
- The WAEC are required to complete Part B of the AAUR which addresses the operation of the WAEC.

7.4 Other reports / information

The WAEC may require any other reports or information from CIs (such as regular progress updates, or further information on an adverse event) either as a condition of approval, or during the project.

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

8.1 Complaints concerning the care and use of animals by institutions

Complaints may also involve non-compliance (refer to section 8.4).

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 WAEC approval, the complaints are referred to the WAEC to investigate whether such activities are conducted in accordance with WAEC approval.

Where a complaint arises from a member of the public, the complaint will be considered by the WAEC 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 [Australian Code for the responsible conduct of research](#), 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 *DPIRD Discipline & Misconduct Procedure - 2018*).

At the discretion of the Chair and/or as directed by the WAEC, an investigation can be undertaken into the complaint by an independently appointed person. Where appropriate, terms of reference will be established by the WAEC or WAEC 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 WAEC's investigation of complaints, the WAEC must:

- ensure that, where complaints relate to activities that would normally require WAEC approval, the activities are reviewed in consultation with all relevant people to ensure that the reason for the complaint is addressed. The WAEC 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 WAEC approval, the matter will be dealt with as a non-compliance (section 8.4).

8.2 Complaints concerning the WAEC process

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

In which case the DG or delegate:

- shall, in the first instance, refer the matter to the WAEC Chair for comment.
- may convene a panel comprising at least the Director General or delegate, WAEC Chair and one external member of the WAEC, 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 WAEC.

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

Where a grievance arises between WAEC members or between WAEC 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 *DPIRD Grievance Management Policy & Procedure - 2018*).

8.3 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.

8.4 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 WAEC, governance officials, and external parties subject to formal agreements.

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

Non-compliance may vary in degree of seriousness from a minor breach of the Code, or conditions of WAEC 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 WAEC Chair as soon as possible. The Chair will determine to notify the WAEC Executive (or full WAEC).
- Actions must be taken to address the issues in consultation with the CI or other person(s) involved.
- At the direction of the WAEC 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 WAEC 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.
- WAEC 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 WAEC 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 Director General or delegate for action in accordance with DPIRD policy and procedures. The WAEC 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 WAEC by addressing concerns raised by the WAEC regarding non-compliance that may include disciplinary action upon the advice of the WAEC.
- DPIRD shall advise the regulatory authorities in writing of alleged breaches of legislation that had a significant impact on animal wellbeing or regarding other serious breaches upon the advice of the WAEC.
- Non-compliance must receive appropriate follow-up.
- The EO must maintain records of non-compliance.
- DPIRD must conduct an annual review of its non-compliance processes.

9. Annual reports and independent external reviews

9.1 Institutional Annual Report

The WAEC shall provide an annual report on its activities and issues over the January to December period including a statement indicating compliance with the Code, to the DPIRD Director General via the DPIRD Scientific Use Licence holder. This report may be provided to other licensed scientific establishments that use DPIRD's WAEC.

The WAEC 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 WAEC approval.
- Activities that have supported the educational needs of the WAEC 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.

9.2 Independent external review

The WAEC is subject to an independent external review (IER) 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 IER 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 IER 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 WAEC. 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 IER 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 WAEC approval.
- The adequacy of DPIRD support, resources and educational programs for the WAEC 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 WAEC 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:
 - o Identify areas of non-compliance.
 - o Support strategies for short-term and long-term continual improvement.
 - o Give recognition to behaviours and actions by individuals and teams that support compliance.

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

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

DPIRD and its WAEC 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)
- 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): WAEC Executive Officer, AWO, AWM and the AEC Chair.

Annual review: DPIRD must conduct an annual review of the operation of the WAEC 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 WAEC processes regarding complaints and non-compliance.

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

The WAEC 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
- 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 – Amendment category 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 the WAEC, WAEC Executive or Chair to approve. All requests will be considered on a case-by-case basis, and the amendment type will be determined by the Chair or Executive. Each amendment can include up to three changes. Where multiple changes are requested on the same form, they will be considered individually. Up to four Major amendments are permitted for a project. If additional major amendments are sought, a new project application will be required.

Reference: The Code (2013) sections: 2.2.23(ii), 2.4.4(iii), 2.4.10, 2.5.15(i), 2.7.6

Amendment Type	Definition (Not exhaustive)	WAEC Process
MAJOR Amendment (WAEC approval) Up to 4 permitted over life of project	<p>Any change to the project's aims/objectives.</p> <p>A significant change to methodology / experimental design / additional invasive procedures.</p> <p>Increased risk of harm to animals, including pain & distress.</p> <p>Changes of Chief Investigator (unless Deputy CI).</p> <p>Project extension > 3 months to 12 months.</p> <p>Change in number of animals > 20% from original approval.</p> <p>Increase of 6 or more additional study sites.</p>	<p>CI must provide explanation and justification for the amendment including potential impact on both animal welfare and the project and submit to the EO for determination by Chair or Executive.</p> <p>CI must provide highlighted or track changes sections on the approved New Project Application form showing all proposed changes.</p> <p>To be considered at the next scheduled WAEC meeting unless exceptional circumstances and deemed urgent, in which case the EO will convene a virtual meeting (email or teleconference) of a quorate WAEC as soon as possible (this does not have to be face-to-face s.2.2.26 the Code).</p>

Amendment Type	Definition (Not exhaustive)	WAEC Process
MINOR Amendment (WAEC Executive approval)	<p>A minor change to methodology / experimental design / additional procedures.</p> <p>Not likely to cause harm to animals, including pain and distress.</p> <p>Project extension < 3 months.</p> <p>Change in number of animals < 20% from original approval.</p> <p>Increase of 1-5 additional study sites.</p>	<p>CI must provide explanation and justification for the amendment including potential impact on both animal welfare and the project and submit to the EO for determination by the Chair or Executive.</p> <p>CI must provide highlighted or track changes sections on the approved New Project Application form showing all proposed changes.</p> <p>To be considered by the Executive out of session and ratified at the next scheduled WAEC meeting.</p>
ZERO Amendment for noting (Chair / Deputy Chair approval)	<p><u>No</u> change to methodology / experimental design.</p> <p><u>No</u> welfare risk indicated.</p> <p>Additional co-worker(s) undertaking approved project procedures such as trapping, spotlighting, observation and routine animal husbandry tasks with competencies provided.</p> <p>A delay of up to 3 months to the start date with the end date extended by the same amount.</p> <p>Use of different sex or age animals or change of location (not additional) where there is no impact on animal welfare and the project.</p>	<p>CI must provide explanation and justification for the amendment and submit to the EO for determination by the Chair or Deputy Chair.</p> <p>CI must provide highlighted or track changes sections on the approved New Project Application form showing all proposed changes.</p> <p>To be considered by the Chair and noted at the next scheduled WAEC meeting.</p>

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