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| Wildlife Animal Ethics Committee -Operating Procedures January 2024 |

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## Review and assessment of new projects

The Executive Officer (EO) and Chair of the Wildlife Animal Ethics Committee (WAEC) shall offer appropriate direction and guidance to proponents to assist with determining whether a proposed activity or project requires WAEC approval. DPIRD’s Interim Policy for environmental scientists gives direction on what procedures need to have ethical oversight. [Environmental scientists interim policy FAQs](https://www.agric.wa.gov.au/sites/gateway/files/Scientific%20Use%20Licences%20for%20environmental%20scientists_interim%20policy%20and%20FAQs.pdf)

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 *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 correct and suitable for assessment by the WAEC members.

#### 1.1.2 WAEC assessment of applications

Only a fully quorate WAEC may approve applications for new projects and activities, and the ongoing approval for existing 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 which:

* Are submitted on a WAEC 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.
* Provide a valid Scientific Use Licence (SUL) number.
* Are signed by the Chief Investigator (CI) and all other relevant signatories as indicated on the AEC proposal application 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 in order to make informed decisions.
* The WAEC 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 captured / handled 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.

### 1.2 Decision-making

Each WAEC 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 should be made on the basis of consensus. 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 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.

**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 and/or Executive (minor revision) or full WAEC (major revision).
* **Not approved** - the proposal is not approved; another new project application is required.
* **Deferred** – a decision is deferred pending the WAEC obtaining further information from either the Chief Investigator and/or other sources.

**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

WAEC 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 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 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.

## Personnel training, competency, and standard operating procedures

### 2.1 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 WAEC project application 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 WAEC members, and over time may become mandatory.

### 2.2 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.

### 2.3 Standard Operating Procedures (SOPs)

The WAEC 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 are available for the WAEC members and CIs to refer to.

The WAEC 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 WAEC. The WAEC must review approved SOPs every three years or when a change to any part of the SOP is proposed.

## Notification of WAEC decisions

The WAEC, 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 WAEC 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 WAEC and signed by the AEC Chair.
* If provisional approval is granted, subject to modifications, the CI will be sent formal notice of the outcome and revisions that must be undertaken 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 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:

Amended to address all concerns raised by the WAEC.

Re-signed by all participants as if a new proposal.

Considered by the full WAEC.

## Amendments to approved projects or activities

No element of an activity may be amended from that as detailed in the WAEC 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 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 AEC.

The Chair will determine if an amendment is for noting (zero amendment), a minor or major amendment (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 WAEC Executive. Amendments for noting only will be determined by the Chair. The full WAEC will be notified at the next AEC meeting.

Amendment requests to the WAEC Executive or full AEC, if the request is urgent, 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.

The WAEC 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 WAEC.

## 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 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 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 WAEC are likely to be undertaken in remote areas, the WAEC 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 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.

## 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 WAEC.

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

### 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 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 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.

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

## Standard reporting of activities by the CI to the WAEC

### 7.1 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.

### 7.2 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 WAEC 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.

### 7.3 Other reports

The WAEC may require any other additional reports (such as an annual progress monitoring report) as a condition of approval or during the project.

## 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 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 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*](https://www.nhmrc.gov.au/guidelines/publications/r39), 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 AEC 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 AEC approval, the matter will be dealt with as a non-compliance (section 14.4).

### 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 DG 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 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 *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 AEC).
* 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 DG 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 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 EO must maintain records of non-compliance.
* DPIRD must conduct an annual review of its non-compliance processes (*clause 2.1.9*).

## 9. Annual reports and independent external reviews

### 9.1 Annual report

The WAEC 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 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 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 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 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 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:

* 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 WAEC must provide a response to the review panel’s final report to DPIRD’s licensee.

DPIRD’s licensee must provide to the DG 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 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 three Major amendments 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

| Amendmenttype | 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. | Chief lnvestigator (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.Cl 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 approval)** | A minor change to methodology/ experimental design / additional procedures.Not likely to cause harm to animals, including pain and distress.Project extension < 3 months. | Cl 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 the Chair or Deputy Chair |
|  | Change in number of animals < 10% from original approval. | Cl 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 nextWAEC 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. | Cl 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. |

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