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JCU Animal Ethics Committee Operating Procedures

1. AEC Scope

a) Activities Requiring AEC Review

All scientific activities involving animals must be reviewed by the James Cook University AEC regardless of the impact the activities have on the animals, where an animal is defined as any living non-human vertebrate (i.e. fish, amphibians, reptiles, birds and mammals) and cephalopods (octopus, squid and nautilus).

The definition includes the following life stages:

- mammal, reptile and bird embryos and foetuses that have progressed beyond half their gestation/incubation period;
- fish and amphibian larval stages once they become free-feeding.

Scientific activities include the following:

- Research;
- Teaching;
- Production of biological products;
- Breeding;
- Population surveys including cameras, boat and aerial surveys;
- Bird, bat and fish banding carried out as a part of university teaching or research.

At JCU it is also a requirement that activities where the animal may not detect their participation in the project, such as camera surveys, aerial surveys and other similar activities, also require AEC approval.

Observational Animal Activities

Observational only activities will be defined as those activities where the activity does not involve the 'use' of the animal, as outlined on the Queensland Regulator's website:

- They involve only observation and recording of information
- Where the animals involved are unlikely to be able to perceive they are being observed, and
- Where the risk to the animals is negligible and there nothing more than a minor alteration to the animals' behaviour or routine as a result, and

An evolving list of observational only activities (Appendix 1) will be maintained and approved by the AEC, with any new activities also approved by the AEC as they arise.

Applications involving observational only activities can use the Observational Activities Application Form, which will only require details of the activity, target species and the justification for conducting the activity.

Researchers wishing to conduct an activity that has been approved by the AEC as being observational only, should email the ethics office for advice on whether to submit the Observational Only Application Form.

Applications involving observational only activities can be reviewed by the Executive outside of a meeting, to be ratified at the following meeting.

Observational activities will be recorded in the ethics database and allocated an approval number, Annual Progress and Final Reports will need to be submitted to the AEC for review, and amendments submitted if there are any changes to the research, but do not require the submission of animal usage numbers annually as they are not reported as animal use to the regulator.

The Australian Code for the Care and Use of Animals for Scientific Purposes and *Animal Care and Protection Act* will still need to be applied to observational only activities.

Non-scientific Activities

Displays, exhibits and general animal holding by JCU staff, while not scientific purposes, are required to have AEC approval if the animal holding is on JCU property. This does not apply to AIMS or other external researchers displays or holding of animals.

Short-term displays or demonstrations involving animals, such as for Open Day, do not require AEC approval as long as:

- They are not part of a research/teaching approval;
- The display/demonstration is not a scientific purpose;
- They are held and cared for in a way that supports their wellbeing; and
- They are returned to normal husbandry conditions as soon as possible after their use in the display/demonstration.

a) Use of the JCU AEC

The JCU AEC will accept applications from the following personnel:

- JCU staff and students;
- JCU adjunct staff (proof of adjunct status must be provided);
- AIMS staff and students;
- AIMS adjunct staff (proof of adjunct status must be provided) or contract researchers upon provision of their agreement with AIMS;
- External personnel or organisations that are too small to be able to form their own AEC, however approval must be sought from the AEC before any formal agreement can be made.

The Principal Investigator (PI) named on the application needs to be someone from the above groups.

b) Agreement to Use the JCU AEC

The JCU AEC allows some external organisations or lone investigators to use its AEC in the following circumstances:

- If it has been approved by the Manager, Animal Welfare and Research Ethics;
- With the agreement of the JCU AEC;
- An agreement to use the AEC is signed;

- Larger organisations that expect to have more than 2-3 active applications per year need to be registered as a Scientific User with QDAF.

The JCU AEC can only accept applications from external organisations or personnel where the proposed work will be in Queensland, as JCU does not have approval to oversee non-JCU researchers in other jurisdictions. Similarly, JCU cannot accept projects from external users wanting to carry out activities in states other than Queensland.

c) Projects Involving More Than One AEC

Where there are collaborations between investigators from more than one institution, an agreement may need to be put in place between the JCU AEC and the AEC of the other institution(s). If an agreement is required, the ethics team will organise these agreements according to standard agreement templates. *(Sections 2.6.4-7)*

d) JCU Staff or Students Working Under the Approval of Another AEC

Investigators must notify the JCU AEC in writing if they are involved in collaborative studies using animals at another institution, or if they are named in an application to the AEC of another institution. The investigator should notify the JCU AEC by emailing ethics@jcu.edu.au and attaching a copy of the application and the approval from the other AEC(s). *(Section 2.4.9).* The JCU AEC wil then acknowledge the approval of the other committee.

e) External Researchers Conducting Research in JCU Facilities

The JCU AEC is responsible for all animals housed on JCU land for scientific purposes. When an investigator from an external institution plans to use or house animals used for scientific purposes on a JCU campus or research station without a collaboration with JCU investigators, the JCU AEC will need to be notified. In these situations, the AEC prefers that the work be conducted under a JCU AEC approval, and an agreement will need to be in place between the JCU AEC and the external institution.

f) Activities that cannot be approved by the AEC include:

a. Projects taking place in the state of Victoria and the A.C.T. as JCU is not authorised to conduct animal research in those jurisdictions.
b. Projects that involve primary or secondary students where the activities include:
    i. Animal breeding that does not achieve educational outcomes and provide for the lifetime welfare of animals;
    ii. Surgical, invasive and other harmful procedures, other than routine husbandry;
    iii. Induction of an infectious disease or illness;
    iv. Production of nutritional deficiency;
    v. Exposure to conditions that would cause an animal to experience pain or distress;
    vi. Administration of drugs or chemicals unless for therapeutic or diagnostic purposes;
    vii. Administration of toxins, ionising radiation or biohazards;
    viii. Humane killing of animals unless it is to achieve an educational objective in science as specified in the relevant curriculum or competency requirement, or as a part of veterinary clinical management of an animal under the direction of a veterinarian.

2. The JCU Animal Ethics Committee

a) AEC Membership

The minimum membership requirements of the Code are, as defined in the Terms of Reference:

- *Chairperson*
- *Category A – Veterinarian*
- *Category B – Investigator involved in the use of animals for scientific purposes*
- *Category C – Animal welfare group representative who is independent of the institution*
- *Category D – A lay person, who has no experience in animal use and is independent of the institution*

Categories C and D will represent at least one third of the AEC membership.

When reviewing items related to projects taking place in South Australia, an animal facility manager will step in to assume the Category E (person involved in the daily care of animals) position.

A Membership Register with appointment dates and end-of-term dates will be maintained by the Animal Ethics Officer.

b) Resources

JCU and Research and Innovation Services will provide adequate resources to ensure the AEC will meet its responsibilities under the Code.

These resources will include:

- Administrative assistance in the form of electronic and administrative systems and an Animal Ethics Officer (AEO);
- An Animal Welfare Officer to provide advice on animal welfare and compliance;
- Free parking for AEC members;
- Reimbursement for out-of-pocket expenses;
- Transport, meals and accommodation to attend inspections of facilities and sites;
- Access to professional development opportunities and conferences.

The Manager, Animal Welfare and Research Ethics will be a veterinarian and act as the University's Animal Welfare Officer (AWO).

The electronic systems used by the AEC include:

- AEC Database, keeping records of all projects and investigators
- Non-compliance and Complaints Register – excel spreadsheet logging complaints, investigations and incidences of suspected non-compliance
- Unexpected Adverse Event (UAE) Register – excel spreadsheet documenting all UAEs
- Facility Inspection Register – excel spreadsheet documenting inspections
- SOP Register – excel spreadsheet for SOPs, their approval and review dates
- 3Rs Register – excel spreadsheet documenting where the 3Rs have been addressed (some jurisdictions ask us to report on our progress in implementing the 3Rs)
- LearnJCU Animal Welfare and Animal Ethics Committee organisation https://www.jcu.edu.au/learn/home
- TRIM record management system for archiving of all documents

c) Recruitment

Members will be recruited to meet the requirements of the Code by either direct approach, by recommendation or through appropriate organisations and groups.

Where the AEC is approached by a potential member, their details and suitability will be kept on record for when an appropriate position becomes vacant.

d) Appointment

Potential AEC members will be interviewed by the Chair and Manager, Animal Welfare and Research Ethics to determine their suitability for the membership.

If successful in the interview, a potential new member will provide a brief resumé and complete the following forms:

- The online EC14 AEC Member/Advisor's Details Form at https://forms.business.gov.au/aba/qldgov3/application-animal-ethics-committee-aec-member-details/
- Nomination Form Membership Animal Ethics Committee
- Nomination Guidelines

Once approval is received from the Queensland Regulator, the new member will be sent the following to complete:

- Letter of Appointment
- Confidentiality of Business Agreement
- Acceptance of Membership Form (needs reviewing, not compliant)
- Declaration of Interests and Conflict of Interest Declaration
- List of meeting dates
- Volunteer Insurance Form (non-JCU members only)

The incoming member will receive a letter from the Chair acknowledging their appointment, thanking them for agreeing to join the AEC and outlining the term of their membership.

New members will be given the *New Member Induction Booklet*, access to all applicable legislation and the Code and receive a formal face-to-face induction into their roles. This induction process will be documented in LearnJCU.

New members will also be given access to LearnJCU *Animal Welfare* and *Animal Ethics Committee* organisations and instructions for their use.

e) Membership Renewal

Two months before the end of term date for a member, the Manager, Animal Welfare and Research Ethics will meet with the Chair and AWO to discuss whether a second term will be offered to the member.

If it is decided to offer a second term to the member, they will be contacted and formally offered the second term and if they accept, they will be sent an *Acceptance Form* to return.

If it's decided that the member will not be offered a second term, a replacement member will be sourced and recruited to start when the position becomes vacant and the outgoing member will be formally notified that their term of office has ended.

f) Resignation and Retirement

Members can resign at any time during their term. Resignations must be made in writing to the Chair.

Approximately two months before a member's second term of office, a search for potential replacements will begin.

After serving two terms of office, members will be notified two months in advance that their term of office will expire, but they may be asked to remain on the AEC until a suitable replacement is able to start.

Outgoing members will receive a letter from the Provost and Chair thanking them for their service and a certificate of appreciation.

At the end of their membership, outgoing members will have their access to LearnJCU removed.

Members can return to the AEC after a hiatus of six months or more.

g) Chair

The Chair will be recruited through consultation with the Divisions, the Provost and through word of mouth, and will either be a senior member of the JCU staff or an external appointment given adequate resources and authority to carry out the role.

The Chair will preferably be someone independent of the care and use of animals for scientific purposes and will not be a member of the AEC, their job will be to facilitate decisions.

Recruitment of a new Chair should preferably begin well before the retirement of the sitting Chair, to allow some room for a handover. Ideally, the new Chair will be chosen from existing AEC members.

The Chair will be officially appointed by the Provost with no fixed term of service.

The Chair will receive a stipend for her service in the report.

h) Acting Chair

At times when the Chairperson is unable to attend, or when the Chair has declared a conflict of interest, an Acting Chair will be appointed to manage AEC business.

i) Notification of Regulators

Regulators must be notified of any changes to the AEC's membership in writing within two working days, and the Manager, Animal Welfare and Research Ethics must be copied into the correspondence or provided with a copy of any electronic confirmation of the notification.

After approval by the Queensland Regulator, interstate regulators should be supplied with the approval notice received from the Queensland Regulator so they can also make a determination about their suitability for their Category.

The NSW regulator uses online forms for changes to membership at:
https://biosecurity.transactcentral.com/Biosecurity/servlet/SmartForm.html?formCode=applicationanimaleth

j) Other Attendees

Managers or staff of animal facilities will be invited to attend AEC meetings as Observers for the term of their employment to provide advice related to the animals in their facilities.

Observers will receive formal invitation to join from the AEC Chair.

Observers are not required to attend all meetings and are not involved in the final decision-making process. They are free to participate in discussions related to the facilities, although should not dominate discussions, allowing the AEC members to have their say.

Facility Managers will be asked to sign the *Confidentiality of Business Agreement* before being given access to the LearnJCU sites, and provided with the AEC's Operating Procedures and the list of upcoming meetings, and added to the AEC meeting invitations.

k) Investigators Attending Meetings

Investigators may be invited to meetings by the Chair to explain or discuss their submissions or provide information within their area of expertise.

3. Animal Ethics Monitors

Animal Ethics Monitors will be academic staff who are currently involved in research and teaching activities involving animals and who have a desire to service the JCU community. Monitors are selected by expertise in a number of areas to ensure coverage of animal usage at JCU:

- Aquatic animals
- Terrestrial wildlife
- Veterinary science
- Biomedical science

Animal Ethics Monitors will be appointed either after being approached or by nomination by their College.

There is no fixed term for monitors, and they may progress to a member of the AEC or resign by providing a written resignation.

Animal Ethics Monitors will receive a formal face-to-face induction and induction pack containing relevant AEC documentation, be invited to attend AEC meetings as observers and receive feedback on the outcomes of the submissions they have reviewed.

4. Executive Committee

The Executive Committee will consist of one member of either Category C or D and the Chair. Its membership will change, depending on the availability of the AEC member or the Chair. An Acting Chair may be consulted if the matter Chair is unavailable and the matter is urgent or if there is a conflict of interest.

The Executive Committee may be delegated to review minor amendments to approved projects or activities.

A minor amendment is defined as one which:

- Does not result in a major change to the aim, direction, outcomes or scientific rigour of the original application;
- Does not significantly increase the impact experienced by the animals;
- Does not significantly increase the numbers of animals required.

Specific amendments that are considered minor, as decided by the AEC, are outlined in Appendix 1.

If the Executive does not reach a consensus decision, then the item must go to the full committee for review and discussion.

Any of the members of the Executive can refer an item to the full committee for review and discussion. Amendments which require large numbers of additional animals cannot be approved by the Executive, and must be reviewed by a quorate meeting of the AEC.

Decisions made by the Executive are provisional only and must be ratified at the next scheduled AEC meeting although ratification is not automatic and the Executive's approval can be overturned by the full committee.

5. Administration of the JCU AEC

a) Submission Forms and Reports

The AEC uses the following submission forms:

- Application for Animal Based Research
- Application for Observational Animal Activities
- Application for Animal Based Teaching
- Application for Animal Breeding Program
- Application for Animal Holding or Display
- Animal Usage Spreadsheet
- Application for Protocol Amendment
- Annual Progress/Final Report
- Unexpected Adverse Event Report
- Standard Operating Procedure Template
- Facility Inspection Report Template
- Project Inspection Report Template
- GM Animal Phenotype Report

Unless by agreement of the AEC, all applications must be submitted on one of JCU AEC's application form for projects being undertaken on JCU property or by a PI who is an employee or student of JCU. For collaborative projects taking place at more than once institution or in the field, it will be decided on a case-by-case basis which AEC's documentation will be used.

b) Review of Documentation

Application documentation will be reviewed annually in January, or as needed to address administrative or regulatory requirements.

c) The Animal Ethics Database

The Animal Ethics Database acts as a project register and stores all the information required by the legislation and necessary to administer the AEC's business and reporting including start and end dates, records of amendments, reports due and received, investigator details, animal usage and meeting or other notes.

Details of how to use the database is outlined in the Animal Ethics Database Instructions.

d) Correspondence

All AEC correspondence related to the operations or submissions of the AEC needs to be sent to the email address ethics@jcu.edu.au.

e) Submission of Documents to Meetings

Submissions must be made by sending an electronic file to the Animal Ethics Officer via ethics@jcu.edu.au.

f) Animal Care Staff Access to Approved Protocols

AEC protocols (final versions of AEC applications and amendments) will be emailed to animal Facility Managers for their records when they are approved that take place in those facilities.

g)

6. Meeting Procedures

a) Meeting Schedule

A meeting schedule for the following year will be drafted for approval by the December meeting (last of the year) showing:

- Meeting dates – first Friday of the month except January;
- Submission deadlines – Close-of-business on the Friday two weeks before the meeting;
- Monitor review dates – The Monday before the submission deadline.

The schedule will be posted on the AEC's website and emailed to AEC members and Facility Managers once it has been checked for clashes with public holidays and other events.

Calendar meetings will be made in the Ethics calendar with invitations sent to attendees.
Rooms and the video conference on both the Townsville and Cairns Campuses will be booked for the meetings.

b) Special Meetings

A special meeting may be required in some circumstances when urgent review of a project or issue is required outside of a scheduled meeting.

Special meetings can only go ahead with the agreement of the AEC members.

Special meetings will be conducted and minuted in the same way as scheduled meetings.

c) Quorum

New proposals can only be approved at a quorate meeting, where there is at least one member from each category present, and categories C and D make up at least one third of the members present.

Two weeks before the meeting, the RSVPs from members should be checked and a determination made about whether there will be a quorum at the upcoming meeting. If a quorum will not be present, the meeting may need to be postponed to the earliest time that a quorum can attend.

If a meeting is postponed, investigators with submissions for review will be informed of the change of meeting date.

d) Agenda

Once finalised the Agenda documents will be uploaded to LearnJCU at least one week before the meeting.

Late items will be uploaded only if absolutely necessary and justification is accepted by the AEC. If there are late submissions the meeting attendees will receive an email notifying them that new items need to be reviewed to ensure those having read the agenda documents earlier don't miss the new items.

LearnJCU contains discussions for each item that allows people to comment or ask questions about the item. The Forums will be checked regularly before the scheduled meeting and any questions

passed onto the investigator so that responses can be received before the meeting and reviewed at the meeting. This will give the AEC a better understanding of the item and prevent the approval being delayed.

e) Minutes

The AEC meeting minutes will be taken during the meeting and finalised as soon as possible after the meeting, and will include:

- List of attendees;
- Record details of conflict of interest and how they were managed, including the times any member left the room;
- Record the meeting start and finish times, and whether and at what time any member left the meeting before it had ended;
- Be written so that any comments from members included in the minutes are de-identified unless the member specifically requests or consents to their name being associated with the comment for example, if they wanted their objection to or opinion on a decision noted;
- Any actions will be noted in the Action Item List attachment.

Minutes will be approved at the next scheduled meeting after confirmation by at least two members who were present at the meeting in question of their accuracy. Any changes that are required will be made, and the Chair will sign the final version.

f) Decision Making

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

Decisions should be based on a thorough, fair and inclusive process of discussion and deliberation by AEC members, facilitated by the Chair and should be made only by those present throughout the discussion.

The Chair's role will be to facilitate a decision by impartially guiding the decision-making process.

Decisions should be made on the basis of consensus. Where consensus cannot be reached after reasonable effort to resolve differences, the AEC should explore with the applicant(s) ways of modifying the project or activity that may lead to consensus. If consensus is still not achieved, the AEC should only proceed to a majority decision after members have been allowed a period of time to review their positions, followed by further discussion.

g) Approvals

Once the AEC has reviewed an application a formal notification of the decision will be forwarded to the applicant by email. No project may commence unless a formal approval notice has been released.

The AEC may also provide copies of ethics approvals and applications to relevant permit bodies.

After reviewing an application, the AEC may:

- **Approve –** the project can commence.

- **Conditionally Approve –** the project is approved in principle, but either requires minor modifications or the AEC requires more information, clarification or answers to their questions before the project can be given final approval.
- **Defer –** the application requires major revisions or changes to the project's methods.
- **Not approved –** the project falls short of the requirements of the Code, is considered unethical or lacks scientific rigour.

h) Duration of approval

Approvals for research and teaching projects is generally for three years, subject to the submission of satisfactory Annual Progress Reports.

If justification can be provided and funding is available, approvals for up to five years can be given. Justification would include that 5 years of funding is available in the form of a five year grant.

For breeding programs, approval is for three years however, perpetual approval may be provided in circumstances where the breeding program is administered at the facility level, all activities are covered by Standard Operating Procedures (which are reviewed every three years) and adequate justification can be provided.

Work cannot begin on a project and amendments cannot be instituted until the investigators have received written notification from the AEC.

i) Notification of Outcomes

All submissions submitted to a meeting will have a formal response sent the investigator notifying them of the outcome of the review or discussion.

All notifications will be drafted within 5 working days of the meeting, beginning with new applications, then amendments.

j) Animal Research Authorities (ARA)

NSW jurisdiction requires that the AEC issues an approval for projects on a document with information prescribed under the NSW legislation. This is called an Animal Research Authority or ARA.

Since no other jurisdiction places legal requirements on these documents, JCU has modified its approval documentation to conform with these requirements, so that approvals for projects are issues as an ARA regardless of where they take place.

k) Ultimate Responsibility for Activities and the Care of Animals

The PI will be the person with ultimate responsibility for the conduct of the project and the care of animals, unless the PI is a student, in which case the person with primary responsibility will be the primary Supervisor of the student named on the application.

l) Amendments

Once approved a project must progress according to the original application. If changes are required, an Amendment Application can be submitted using the appropriate form.

Retrospective approval for the collection of voucher specimens or for opportunistic sampling of species not listed on the AEC approval can be provided in line with the AEC's *Opportunistic Sampling, Vouchering and Amendments to Projects in the Field Policy*.

7. Conflicts of Interest

On appointment to the AEC all members will need to sign a *Declaration of Interests and Conflict of Interest Declaration*. If any conflicts are declared, the Manager, Research Integrity and Ethics and the Chair will decide what actions may be necessary to manage the conflict or whether their membership will not be tenable.

Any attendees with a conflict of interest around any of the items to be discussed must declare their interests at the beginning of the meeting so that a decision can be made about how to manage it best.

When a member has an agreed conflict of interest, they must leave the room during deliberations regarding that item. For decisions to continue to be made there must still be a quorum remaining in the room.

The conflict of interest and method of management, including that the person left the room will be recorded in the minutes.

8. Confidentiality

All of the AEC's discussions and documentation are confidential and for the use of that committee only, not for general circulation within or outside the University and may not be disclosed or reproduced in whole or in part without the express approval of both the AEC Chair.

Documentation related to specific projects can be provided to researchers named on the protocols or with the written approval of the PI.

9. Animal Ethics Monitor Review Process

Animal Ethics Monitors provide a peer pre-review and act as a source of advice to applicants to the AEC. Their role includes:

- Review AEC submissions that relate to their area of research and provide guidance and advice to the AEC on the scientific integrity of the project;
- Review AEC submissions and provide advice to the submitting investigator about whether it meets the requirements of the Code and the AEC in order for them to address any issues before the meeting that may prevent the application from being approved;
- Provide guidance to investigators wishing to apply to the AEC on matters related to the application and the requirement of the Code and AEC.

It is not compulsory for investigators to seek a monitor review for their submissions, but it is highly recommended to improve the quality of the application.

Submissions should be sent to the monitor at least one week prior to the general AEC meeting closing dates to prevent the monitor from being overwhelmed with last-minute reviews, although the monitor may agree to review a submission after this deadline.

Any comments from the monitor should be addressed in a revised version of the application before it goes to the AEC.

If the monitor has indicated the submission is not suitable to go the AEC, the investigator can contact the AWO who can work with the investigator to rewrite the application. Any comments from the monitor should be addressed in a revised application before going to the AEC.

10. Interstate Animal Use and Registration Requirements

JCU has approval to carry out animal work in four Australian jurisdictions: Queensland, the Northern Territory (NT), Western Australia (WA) and New South Wales (NSW), South Australia (SA) and Tasmania, which means that the AEC may have to assess applications under different pieces of legislation. Since each of these jurisdictions has slightly different requirements, when an interstate project is being reviewed, the AEC staff will provide any additional information necessary for the AEC to make their decision.

Details of scientific animal use approvals

Jurisdiction	Duration
QLD	Three years
NT	Three years
WA	One year
NSW	Three years
TAS	One year
SA	Two years

Reporting

Jurisdiction	Due date	Regulator	Documentation	Website
QLD	31 May	Department of Agriculture and Fisheries	Animal Use Spreadsheet	DAF
NT	30 June	Animal Welfare Branch, Department of Primary Industries	A report containing the information outlined in the NT Annual Report Template	DPI
WA	30 April	Scientific Licensing, Department of Food and Agriculture	Animal Ethics Committee Annual Report Animal Use/Supply statistics	DPIRD
NSW	31 March	Animal Welfare Unit, Department of Primary Industries	Form L – Animal Use Statistics NSW Animal Use Statistics Excel Spreadsheet Template	DPI
NSW	31 December		List of all projects approved in NSW Format not specified, table or spreadsheet acceptable	
NSW	As necessary		AEC Application Forms must be approved by the ARRP if changes are made to them	
TAS	31 May	Department of Primary Industries, Parks, Water and the Environment	Animal Use Report (template) Animal Research Data Entry (spreadsheet)	DPIPWE
SA	31 March	Department for Environment and Water	Annual Report to Institution	DEW

Note: Reminder emails are sent out before reports are due and requirements may change annually so ensure that websites and reminder emails are checked for any changes to reporting processes.

11. Pilot Studies

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 on the basis of available evidence, the incorporation of a pilot study into the design of the project must be considered.

Pilot studies, where proposed, should be regarded as integral to the overall project, especially to enable assessment of the feasibility of the project and the potential for refinement and reduction. They must be assessed by the AEC according to the criteria applied to project approval

A pilot study is incorporated into the design of the project if the potential impact on the animal cannot be predicted on the basis of available evidence, to allow staged assessment of the impact on animal wellbeing and the development of strategies to avoid or minimise any adverse impact

12. Tissue Sharing

In order to meet requirements of the 3Rs, tissue sharing will be facilitated through the AEC's Tissue Sharing Forum in the LearnJCU Animal Welfare organisation.

13. Animal Re-use, Re-homing, Sale and Release

The re-use, rehoming, release or return of animals to normal husbandry after their use raise certain ethical issues and the AEC will review these in line with the *Re-use, Rehoming, Sale and Release Procedure.*

14. Standard Operating Procedures (SOP)

Where a procedure or technique is used in an animal research or teaching protocol an SOP may be submitted in place of providing a description in the body of the application.

Before drafting a new SOP, search the catalogue of existing approved SOPs to see whether the procedure/technique is already described in a SOP.

If no SOP exists, a SOP can be drafted using the approved AEC SOP Template, and should provide enough detail in lay terms to allow the AEC understand.

When submitted, the AEO will allocate a SOP number to the SOP to allow it to be referenced, and then upload it to the meeting site in LearnJCU for review.

SOPs will be made available to all investigators unless it is decided that they contain material that is of a sensitive nature or must be kept confidential for IP reasons, in which case the SOP will be provided 'Restricted' status.

Once approved the SOP will be uploaded in the LearnJCU Animal Welfare organisation where it will be available to investigators, animal care staff and the AEC and this will also be used for the AEC's Training and Competency Program to document investigator competency and training records.

SOPs will be approved for 3 years, after which they must be reviewed and resubmitted, or they will expire and so can no longer be used. The author will be contacted to revise the SOP before it is reviewed by the AEC to determine whether there have been changes to the procedure described since it was last approved.

When used in a protocol application, the SOP number and title can be referenced in place of providing the description. If the procedure to be used in a specific project is going to be slightly different to how it described in the SOP, the variations can be outlined in the application.

15. Inspections and Monitoring of Animal Use

a) Facilities

All facilities that hold animals are overseen by the JCU AEC and will be inspected by the AEC at least annually.

A list of current facilities and sites requiring inspection and contact details is in Attachment 2 and details of inspection dates is in the Inspection Register.

At least one AEC member, preferably a Category C or D, should attend each inspection, but if an AEC member can't attend the AWO or a delegate with the appropriate experience can attend and report back to the AEC.

The inspections will audit the facilities for compliance with the sections of the Code that deal with facilities and animal care.

The AEC will also check the welfare of the animals, inspect projects to ensure they are being conducted as outlined in the project application and that all projects have current approval. This includes animal monitoring and records keeping.

Facility inspections reports will be written on the Facility Report template by the AWO.

Once drafted, the reports will be circulated to the other members of the inspection team to ensure that it is complete and reflects what was seen on the inspection.

It will then be sent to the Facility Manager, so that they can correct any minor inaccuracies, but the Manager cannot request removal or changes to the findings of the inspection team.

Once complete the report will be reviewed by the AEC at a meeting to be ratified or for extra comments to be included.

The report can then be sent to the Division for review, and to respond to any findings.

A list of JCU Animal Facilities and contact details can be found in Appendix 2.

b) Fieldwork

Field sites can be inspected by the AEC, a delegate or by video or photographs as a condition of approval for a project.

c) Animal Project Compliance Audits

The AEC or AWO may conduct compliance audits of individual projects.

The audits will be looking more closely at whether a project is being conducted in compliance with the legislation, the Code and the AEC approval and look at monitoring records, drug registers and any other records required for review.

d) Annual Progress Reports

Annual Progress Reports must be submitted to the AEO by the 31 March each year using the appropriate form and spreadsheet.

Failure to submit an Annual Progress Report will result in termination of approval for the project.

Reports will go to the AEC and following review of the report for a project the AEC will decide whether adequate progress is being made and whether the project can continue for another year.

e) Final Reports

At the completion of a project, a Final Report must be submitted to the AEC using the report template and animal use spreadsheet.

The AEC may refuse to review future applications from that investigator or student's supervisor until the report is received.

f) Unexpected Adverse Events (UAEs)

UAEs, as defined by the Code, must be reported to the AEC within 48 hours. This can be done informally if the investigation into the UAE is not complete, and then followed up with the formal report on the JCU AEC UAE Report template.

The review of UAE reports by the AEC is another way the AEC can monitor the care and use of animals and compliance.

On receipt of an UAE report, the report will be given a reference number and forwarded to the AWO for an initial review to determine whether urgent action is required to ensure animal welfare or if more information is required.

If the AWO feels that the circumstances of the UAE may represent a threat to the wellbeing of other animals, the AWO may, after consultation with the Chair, intervene in order to support the wellbeing of these animals.

The AEC will review the report at the next meeting and provide feedback to the investigators.

g) JCU New Facility Planning and Facility Renovation

The AEC needs to be consulted in the planning of new facilities and refurbishment or modification of existing facilities.

No animals can be housed in a new, refurbished or modified facility until the AEC has conducted an inspection of the facility.

h) Annual Review of Compliance with the Code

An annual review of compliance with the Code will be undertaken through the submission of a report to the Provost.

The report will follow a standard template that needs to be compliant with the Code and NSW and WA requirements for an annual report.

Shortly after submission of the report to the Provost, a meeting will take place between the Manager, Animal Welfare and Research Ethics, the Chair and the AWO to discuss its contents, recommendations from the AEC and any other AEC issues.

A modified report will be provided to AIMS to cover their projects overseen by the AEC.

The report must also be submitted to the WA and NSW regulators as a part of the annual reporting requirements for those jurisdictions or by request.

16. Program of Veterinary Care

The Program of Veterinary Care will be co-ordinated by the AWO, and will aim to ensure that veterinary advice and treatment will be available to all animals used by JCU staff and students.

Veterinarians involved in the program include:

- The AWO – will be a veterinarian and will co-ordinate the program and ensure that it complies with the expectations of the Code, as well as be available to provide veterinary advice and services to investigators and animal facilities;
- Category A members of the AEC – will be involved in the review of research proposals, monitoring of animal care and use including animal facility inspections;
- JCU veterinary academic staff – are available to provide veterinary services as required according to their own expertise and availability;
- JCUVet teaching hospital and Townsville Veterinary Hospital veterinarians – will be called on to provide veterinary services as a back-up to JCU veterinary;
- External veterinarians – will be called on to provide veterinary services or monitor remote research as required, for animals at field sites or research stations.

For field research, investigators should outline how they will access veterinary care in the Contingency Plan section of the AEC application.

17. Animal Welfare Concerns or Complaints

a) Making a Complaint or Raising an Animal Welfare Concern

Complaints or concerns about animals used by JCU, in relation to the conduct of investigators or animal care staff working under the oversight of the JCU AEC should be made to the AWO, the AEO or the Chair.

Anyone can raise a concern or make a complaint in relation to the conduct of investigators or animal care staff working under the oversight of the JCU AEC.

Complaints or concern can be made anonymously but this may limit the investigation and the ability to verify facts and uncover evidence. All complaints and/or concerns are confidential however the identity of the complainant may become evident or need to be revealed during the investigation, in which case the complainant will be contacted and the issue discussed.

Once raised, the complaint/concern will be documented, given a Reference Number and the details entered in to the Non-Compliance and Complaints Register. All complaints/concerns will be investigated promptly by the AWO, confidentially according to the principles of procedural fairness/natural justice and without disadvantage to the complainant or investigator (when made in good faith).

Complaints and animal welfare concerns will be investigated promptly by the AWO.

b) Complaint Investigation

In relation to a complaint or non-compliance investigation, procedural fairness will be ensured by:

- Following these procedures, which have been established and approved and are fair to all involved;
- Ensuring the investigation is conducted objectively, free from bias, influence and coercion;
- Ensuring that the subject of the investigation is aware of the investigation and its details and has been provided the opportunity to respond;
- Ensuring that only objective, credible, relevant and significant evidence and its summary are provided to the AEC, who will make the final decision to uphold the complaint and take action.

The AWO will undertake an initial informal investigation to verify details provided by the complainant, and if found necessary, a formal investigation will be undertaken.

The complaint may be closed if it is established through the informal investigation that there is no basis for the compliant or there is insufficient information to proceed.

If the complaint/concern is immediately affecting the wellbeing of animals, after consultation with the Chair, the project's approval may be suspended and/or action taken to ensure that the wellbeing of any animals.

The aim of the formal investigation is to gather evidence: undertake interviews with personnel, collect photos, videos, audio recordings, documents and records to prepare a report for the AEC.

Records of all communications including formal interviews will be documented and confirmed by the person who provided them for confirmation of accuracy. This confirmation will be in writing and be done in person using a signature or via email.

Once the investigation is complete, the report can be drafted and all parties given a chance to respond before it goes to the AEC.

c) AEC Review of Investigation

The AEC will review the investigation report in a quorate meeting as soon as possible after the investigation in completed to determine whether there had been a breach to the Code or the AEC approval.

The AEC will then decide whether there is evidence to support the complaint/concern and what action will be taken.

Where complaint/concern raise the possibility of research misconduct as described in the *Australian Code for the Responsible Conduct of Research*, the complaint will be referred to Research Integrity.

Where complaint/concern raise the possibility of misconduct that falls outside the range of research misconduct, as described in the *Australian Code for the Responsible Conduct of Research*, the complaint will be referred to the Provost.

The AEC will then determine whether other actions are warranted, such as:

- Allowing the resumption of research (conditionally or unconditionally);
- Issuing a formal reprimand or warning;
- Continuing the suspension of the project pending further investigation and discussions, or amendments to the research;
- Terminating the project approval and;
- Referring the matter to the external organisation or another body for further or alternative action to be taken.

In cases of serious non-compliance, the regulator and/or funding bodies may need to be notified. The complainant and subjects of the complaint/concern will be notified of the outcome of the AEC review as soon as possible after a decision has been made.

18. Complaints Concerning a Decision Made by the AEC or an AEC Policy

Whether an AEC member, investigator or other person, if someone wishes to question or appeal a decision made by the AEC or an AEC policy or process, they should contact the Animal Ethics Officer or Animal Welfare Officer to discuss the matter or submit a formal complaint to ethics@jcu.edu.au.

If the matter remains unresolved after these discussions the matter may be referred to the Chair for advice, and then to the AEC.

If the matter then remains unresolved the matter will be referred to a person or people external to the AEC but with experience in animal ethics processes and the Code to review the process by which the decisions were made.

The ultimate decision regarding the ethical acceptability of an activity lies with the AEC and must not be overridden by the institution, however if someone is not satisfied with the final outcomes can take their complaint to the Queensland Civil and Administrative Tribunal.

19. Training and Competency Program

To meet the competency requirements of the Code, the AEC will oversee the Training and Competency Program.

This will be SOP and procedure-based and be outlined in the Training and Competency Procedure and documented in LearnJCU using competency declarations.

20. Institutional Policies Related to the Use of Animals Scientific Purposes

Follow the links below for details of JCU's policies related to the use of animals for scientific purposes.

- Workplace Health and Safety – for policies, procedures and access to online systems related to workplace health and safety for work being carried out at JCU or at field sites;
- Drugs and Poisons – for details on requirements for research involving the use of restricted medicines, drugs and poisons;
- Privacy – for procedures related to information privacy;
- Freedom of Information – for information on accessing or responding to freedom of information requests and the requirements related to freedom of information.

Appendix 1

Minor Amendments Allowed to be Considered by the Executive Committee

The JCU AEC considers that amendments to the following are minor and so meet the requirements of the under *Section 2.2.23(ii)* of the Code and can be delegated to the Executive Committee for review outside of a meeting.

Examples include:

- Change to personnel
- Time extensions of less than one year
- Changes to administered substances where the new substance is administered in a similar way and has similar actions and side effects eg types of analgesia or anaesthesia
- Minor experimental design changes with no effect on animal welfare
- Changes to strain, breed or species where there is no change to welfare or conservation status
- Where the change addresses one or more of the 3Rs

General

Any change that addresses the 3Rs eg the replacement of animals with an alternative method, changes in methods that improve animal wellbeing or result in a decreased impact on the animals

Administration

Time extension of less than 1 year as long as the original approval is 3 years or less and no previous time extensions have been approved

Personnel

Addition or removal of personnel
Change of PI

Research Sites

Addition of new research locations or facilities
Removal of research locations or facilities

Housing and Husbandry

Changes to housing, husbandry or feed that meet routine practice for that species and will not affect animal wellbeing.

Animal Usage

Change or addition of species where new species are of similar conservation status
Change or addition of strain of rodents
Change or addition of GM line of rodents (as long as the phenotype is known and complete Phenotype Report is also submitted)
Change or addition of a breed of animals
Change or addition of the sex of animals

NB addition of new types of animals as above can only be considered minor if there is no overall increase in animal numbers and adequate justification is provided.

Methods

Change of anaesthetic or analgesic
Change of administered non-experimental therapeutic agent eg antibiotic
Change of route of blood sampling to another approved method for that species

Change of administered substances, where the new substance is administered in a similar way and has similar actions and side effects
Change in route of administration where the proposed route is of similar impact to the approved route
Increases in blood volume sampled as long as they have shown it's within the guidelines for a safe sample

Appendix 2

JCU Facilities and Contacts – January 2019

Townsville

Immunogenetics Research Facility (Building 31)	Serrin Rowarth – Manager, Small Animal Operations E: serrin.rowarth@jcu.edu.au X: 16460
AITHM New Rodent Facility	
Small Animal House (Building 87)	
Bush House (Building 70) – Rodents	
Bush House (Building 70) – Frogs	Project based, see facility doors for details of user, contacts and project
Bush House (Building 70) – Other	Project based, see facility doors for details of user, contacts and project
MARFU	Ben Lawes – Manager MARFU E: ben.lawes@jcu.edu.au X: 15491
Veterinary Precinct – Pens/paddocks/rooms	Chris Joone – Team Leader, Facilities and Technical Support (Vet Sciences) E: josephine.penny@jcu.edu.au X: 15558
Veterinary Precinct – Aquaculture	Bethany Adomanis – Laboratory and Technical Support – Aquaculture E: bethany.adomanis@jcu.edu.au X: 13623
Turtle Health Research Facility (The Caraplace)	Ellen Ariel – Researcher/Manager E: ellen.ariel@jcu.edu.au X: 14123
AITHM (Building 47) Labs	Lynn Woodward – Lab Manager, AITHM E: lynn.woodward@jcu.edu.au X: 15180
Building 28 – Constant Temperature Rooms	Project based, see facility doors for details of user, contacts and project
The Science Place – Displays	Lexie Edwards – Team Leader, Laboratories and Technical Support E: lexie.edwards@jcu.edu.au X: 15466
The Science Place – Other Projects	Project based

Cairns

Building E5 – Rodent Facility	Serrin Rowarth – Manager, Small Animal Operations E: serrin.rowarth@jcu.edu.au X: 16460
Building E1 – Aquarium	Jamie Seymour – Manager, Associate Professor E: jamie.seymour@jcu.edu.au X: 21229
Building E1 – Displays	Sue Kelly – Manager, Laboratories and Technical Support E: susan.kelly@jcu.edu.au X: 21456

Orpheus Island Research Station	Bec Tite –Manager E: bec.tite@jcu.edu.au or orpheus@jcu.edu.au X: 13480 or 0429 274 485
Fletcherview Research Station	Martin Holzwart – Manager E: martin.holzwart@jcu.edu.au P: 4787 2839

External

AIMS	Craig Humphrey – AIMS SeaSim Precinct Manager E: c.humphrey@aims.gov.au P: 4753 4242
Lizard Island Research Station	Lyle Vail – Director E: lyle.vail@austmus.gov.au P: 4060 3977

Appendix 3

Approved Observation Only Activities

- Visual surveys/direct observation
- Bird watching
- Spotlighting with a light no stronger than a 30 watt/50 watt bulb??? Time limit??
- Call backs?
- Anabat detector surveys of bats
- Unbaited camera traps
- Unbaited underwater video/photographic surveys
- Hair tubes? (baited always?)
- Unbaited video cameras
- Aerial surveys plane/helicopter – altitude/distance from animal
- Aerial surveys drone – Altitude/distance from animal
- Searching/recording animal tracks
- Recording animal tracks in a shallow sand pan
- Non-invasive collection of faeces or feathers
- Audio recordings