# Animal Ethics Committee

# The AEC Approval Lifecycle

*A refresher for Principal Investigators*

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# Contents

*This booklet is organised into seven modules. Each module addresses a specific obligation across the AEC approval lifecycle. Page numbers below are indicative; use Word's navigation pane for cross-referencing.*

# About this booklet

This booklet sets out what the Australian Code, Queensland legislation, and JCU institutional policy require of a Principal Investigator (PI) across the full life of an animal ethics approval — from initial application through to project close — with particular emphasis on the obligation of continuous coverage for animals held under a scientific approval.

It is paired with the GECO Training Booklet, which covers the platform you will use to discharge these obligations. The two booklets are intended to be read together. Where the GECO booklet says, "Submit by the 60-day mark," this booklet says, "because the Code does not permit you to work, hold, or maintain animals without an in-force approval."

This booklet is required reading for any PI completing targeted retraining imposed under the JCU AEC Non-compliance Procedure (Step 3 of the Sanctions Ladder). It is also recommended for any PI on commencement, on transfer between institutions, or on inheriting a teaching approval from a previous PI.

### Why this booklet exists

Approvals at JCU expire. Animals do not. Animals used for a scientific purpose must be covered by an in-force approval throughout their entire holding period — including during routine husbandry, between teaching activities, and on long-term holding for Reduce / Reuse purposes. This booklet exists because the gap between "the project is over" and "the animals are not" is where institutional non-compliance most often occurs.

> **Key principle — coverage, not activity**
>
> The Code does not permit an institution to hold animals for a scientific purpose without a current AEC approval. It is the holding that requires coverage, not only the active manipulation.
>
> If you have animals on site and they were acquired for, or are being maintained for, a scientific purpose, they must be covered by an in-force AEC approval at all times — even when no procedures are being performed.

# Module 1 — The regulatory framework at a glance

**Learning Outcome**

By the end of this module, you will be able to name the four instruments that govern animal use for scientific purposes at JCU and explain how they relate to one another.

## 1.1 The four instruments

- **Australian Code for the Care and Use of Animals for Scientific Purposes (NHMRC, 2013, 8th ed.) — "the Code" —** The instrument that defines what constitutes scientific animal use, sets out the 3Rs (Replacement, Reduction, Refinement), and prescribes the obligations of institutions, AECs, and investigators. Activities involving animals for scientific purposes must be approved by an AEC before they commence and must cease at the expiry of approval unless a current renewal or replacement is in force.
- **Animal Care and Protection Act 2001 (Qld) — "the Act" —** the state-level statute under which scientific animal use is regulated in Queensland. Part 5 requires that use of animals for scientific purposes is conducted under registration and in compliance with the Code. The Chief Executive of Biosecurity Queensland is the regulator.
- **The AEC approval itself —** authorises specific work for a specific period under specified conditions. The approval is the operational instrument; conditions on the approval are binding.
- **JCU institutional policy —** JCU Non-compliance Procedure, Post-Approval Monitoring (PAM) Procedure, Records Management Policy, and Conflict-of-Interest Policy, all of which sit on top of the Code and the Act.

## 1.2 How they fit together

Think of it as four layers, each binding on the layer below. The Code defines what good ethical practice looks like. The Act gives the state the power to enforce it. The AEC approval translates the Code into a specific authorised activity. JCU policy operationalises the institution's obligations under all three. If any one of the four is breached, you are in non-compliance.

**Important**

A finding of non-compliance does not require breach of all four instruments. A breach of the AEC approval alone — for example, working outside the approved species, beyond the approved expiry,

or with non-listed personnel — is sufficient grounds for a non-compliance finding, irrespective of whether welfare outcomes are good.

# Module 2 — Why AEC approval is required, and what it covers

**Learning Outcome**

By the end of this module, you will be able to articulate why AEC approval is required, what counts as "scientific use," what counts as "an animal" under the Code, and the boundary between covered and uncovered activity.

## 2.1 What is "scientific use"?

The Code defines scientific purpose broadly: all activities conducted with the aim of acquiring, developing, or demonstrating 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.

Teaching is scientific use. Demonstrating a procedure on a live animal in a coursework practical is scientific use. Holding a cohort for use in a future teaching practical is scientific use. Maintaining a long-term Reduce / Reuse cohort for possible re-deployment is scientific use.

## 2.2 What is "an animal" under the Code?

Any live non-human vertebrate (fish, amphibians, reptiles, birds and mammals — encompassing domestic animals, purpose-bred animals, livestock, and wildlife) and cephalopods. A live pre-natal or pre-hatched creature is also captured where it is in the last half of gestation, a mammalian or reptilian foetus, or a living marsupial young.

## 2.3 What an AEC approval covers

- the species, strains and numbers approved (and not others).
- the procedures, anaesthesia, analgesia and humane endpoints approved (and not others).
- the personnel approved (and not others).
- the facility and location approved (and not others).
- the period approved — the start date through to the expiry date (and not beyond).

If an activity falls outside any one of these dimensions, it is not covered by the approval. Doing it anyway is non-compliance — even where the intent is benign and the welfare outcome is good.

# Module 3 — The approval lifecycle, end to end

**Learning Outcome**

By the end of this module, you will be able to describe each stage of the AEC approval lifecycle and your obligations at each stage.

## 3.1 The seven stages

1. **Pre-application —** plan the work; identify the species, numbers, procedures, personnel and location; draft the application in GECO.
2. **Application and review —** lodge in GECO; respond to AEC queries; receive determination.
3. **Approval —** approval issued, always with conditions. Conditions are binding.
4. **In-force conduct —** work proceeds within the scope of the approval; personnel changes, animal numbers, and procedural variations are managed through amendments.
5. **Annual reporting —** annual report lodged each year on the anniversary of approval; the AEC reviews and ratifies.
6. **Pre-expiry decision —** it is recommended that 120 days before the recorded expiry, the PI decide whether to (I) close the project (final report); (II) extend the project by amendment where the work is largely complete; or (III) lodge a renewal or consolidated replacement application where the work continues.
7. **Closure —** final report lodged; animals disposed of, transferred under a new approval, or confirmed not held under the closed approval; AEC closes the file.

**The 120-day rule**

Treat the 120-day pre-expiry mark as a hard decision point on your own calendar, independent of any system reminder. Decide on that day whether you will close, extend, or replace — then act. Approvals do not extend themselves, and AEC review takes time.

# Module 4 — Continuous coverage: animals held under a scientific approval

**Learning Outcome**
By the end of this module, you will be able to state, in your own words, the continuous-coverage obligation and apply it to the routine situations in which JCU PIs find themselves.

## 4.1 The obligation in one sentence

Any animal acquired for or maintained for a scientific purpose at JCU must, at every moment of its life under JCU's institutional responsibility, be covered by an in-force AEC approval that authorises its holding under the conditions in which it is held:

1. All subsequent records and correspondence relating to the project must refer to the ethics approval number.
2. All work will be carried out in compliance with the approved protocol and the application summary and according to the directions of the James Cook University Animal Ethics Committee.
3. That there is NO departure from the approved protocols unless prior approval has been sought from the Animal Ethics Committee.
4. Approval is conditional on the submission of a satisfactory Annual Progress Report. Non-compliance with mandatory reporting requirements will lead to revocation of approvals granted by the AEC. This report must also detail animal usage, and any unexpected events that may have occurred during the study. For fieldwork activities, video or photographic evidence must be provided to the Animal Ethics Committee with the Annual Progress Report in order to meet the requirements of Sections 2.3.17-23 of the Australian code for the care and use of animals for scientific purposes.
5. A Final Report must be submitted upon the completion of the project.
6. The Principal Investigator must advise the Animal Ethics Committee within 48 hours after the occurrence of an Unexpected Adverse Event, and submit an Unexpected Adverse Event Report as soon as possible after the event.
7. Research activities involving wildlife studies must provide a copy of the JCU animal ethics approval and application to the Queensland Department of Environment and Heritage Protection (EHP). Once the EHP permit is received, it must be provided to the Animal Ethics Committee.

## 4.2 Why "in-force," not "issued at some point"

- An expired approval is not a current authorisation. The Act, the Code, and JCU policy all treat an in-force approval as a different state from a closed or expired approval. An expired approval is closed;

you cannot draw current authority from it any more than you can drive a car on a licence that lapsed last year.

- This is true even where the activity being conducted is identical in scope to what the expired approval previously authorised. The activity may not have changed; the authority has.
- It is also true even where animal welfare has not deteriorated. The Code obligation runs on coverage of holding and use, not only on welfare outcome. Good welfare under an expired approval is still unauthorised use under the Code.

## 4.3 Routine examples

- **Long-term teaching animals —** a teaching cohort must be covered for the entire period it remains on site, including between practicals, including over the holidays break, including while no new animals are being introduced.
- **Reduce / Reuse cohorts —** animals held in long-term storage for possible future re-deployment under Reduce / Reuse — covered for the entire holding period, even if no procedures are being performed.
- **Breeding colonies —** breeding stock are still animals held for a scientific purpose — covered for the entire period they are on site.
- **Wildlife held in transit —** a wild animal captured for a scientific study and held in transit pre-release — covered from capture to release.
- **Transferred cohorts —** a closed project that is being replaced by a new project — the cohort's coverage must transfer cleanly to the new approval; gaps in coverage between the old and new approval are non-compliance.

# Module 5 — When the approval has already lapsed

**Learning Outcome**
By the end of this module, you will know exactly what to do — and what not to do — if you discover, or are told, that an approval has expired and animals are still being held under it.

## 5.1 Immediate steps (within 24 hours)

- Cease all activity under the expired approval, except for routine husbandry necessary to maintain welfare. Cancel any scheduled teaching delivery or experimental procedures under the affected approval until coverage is restored.
- Notify the AWCO in writing, copying the Manager, Research Ethics and Compliance (ethics@jcu.edu.au). State the approval number, the date of expiry, the species and numbers of animals affected, and the activities that have continued in the lapsed period.
- Notify the facility manager so that the facility can take its own compliance steps and so that routine husbandry can continue under appropriate oversight.
- Provide a written undertaking, on file with the Ethics Office, that no further teaching delivery, new procedures, or new animal intake will occur under the affected approval pending submission and AEC approval of the replacement application.
- Submit a consolidated replacement application in GECO as a matter of priority. Identify it as a Consolidated Replacement Application and link it to the expired approval number.

## 5.2 What NOT to do

- Do not continue teaching delivery or new procedures “while we wait for the replacement.” The expired approval cannot authorise anything. Welfare-good husbandry to maintain animals already on site is a different category from new procedural use.
- Do not lodge an amendment to the expired approval. An amendment cannot revive an expired approval. The required instrument is a new or consolidated replacement application.
- Do not assume the matter is closed once the new approval is issued. The lapsed period itself is still a non-compliance and will be assessed under the JCU AEC Non-compliance Procedure.
- Do not silently rectify. Even where the new approval is in flight, the lapsed period must be self-reported under §5.5 of the Non-compliance Procedure. Failure to self-report a lapse you have identified is itself a basis for additional sanction.

### Why self-reporting matters

Voluntary self-report of a non-compliance BEFORE detection by monitoring, audit or complaint attracts a −1 step modifier on the Sanctions Ladder (Non-compliance Procedure §7.2 and §9.2).

Acknowledgement AFTER detection — including after an AWCO inspection identifies the lapse — does not attract the formal credit. The credit is earned by being the first to disclose, not by being honest once asked.

# Module 6. Post-approval monitoring: how coverage is verified

**Learning outcome**

After this module you will know what Post-Approval Monitoring (PAM) is, how the AWCO verifies that animal use at JCU continues to match what was approved, and what your obligations are as a PI when PAM activities occur.

## 6.1 Why PAM exists

The Code (cl. 2.4.30–2.4.34) requires institutions to have systems in place to confirm, on an ongoing basis, that approved animal use is being conducted in accordance with the AEC's authorisation. PAM is JCU's discharge of that obligation. It is not optional, and it is not a peer-review exercise. It is the institutional control that lets JCU say, on the record, that the animals held under its registration are being held and used under in-force approvals, in the manner approved, by the personnel approved, in the facilities approved.

The continuous-coverage obligation set out in Module 4 is the substantive requirement. PAM is how compliance with that obligation is verified.

## 6.2 How monitoring frequency is set

Every approved project is assigned a PAM risk score after approval, derived from five factors: procedure severity, animal numbers, species, personnel experience, and compliance history. The total score determines monitoring intensity, higher-risk projects receive unannounced inspections and an annual compliance audit; medium-risk projects receive occasional inspections and an annual desk review; lower-risk projects receive an annual desk-based review. Risk ratings are not fixed and are reviewed whenever a project changes meaningfully, recurrent unexpected adverse events, verified complaints, identified non-compliance, amendments that increase animal impact, or personnel turnover greater than thirty per cent.

## 6.3 The five PAM activities

- Desk-based review: document check at the project anniversary or following risk reassessment, covering annual reports, UAE reports, animal-use records, training currency, and monitoring records.
- First 90-day review: short desk-based check on moderate-risk and higher projects that the project has commenced correctly: approved personnel only, labels in place, records opened, training current.
- Facility inspection: scheduled or unannounced site visit; welfare, recordkeeping, biosecurity, Schedule 8 management, and physical containment are all in scope. Higher-risk projects receive predominantly unannounced inspections by institutional design.
- Targeted review: triggered by a specific event: a UAE of moderate severity or worse, a verified complaint, mortality greater than ten per cent above approved baseline, a Schedule 8 reconciliation discrepancy, an approved humane endpoint reached without the pre-approved intervention being applied in time, or three or more minor amendments within twelve months.

- Compliance audit: comprehensive review for higher-risk projects, comparing the approved protocol against actual practice and including a deliberate check for protocol drift (cumulative small changes that were never formally amended).

## 6.4 How PAM findings are handled

Every PAM finding (If required) receives a unique CAPA (Corrective and Preventive Action) identifier in the JCU CAPA Register at the moment it is recorded and is tracked from detection to verified closure. CAPA actions cannot be closed on PI self-attestation alone; objective evidence of effectiveness is required. This is a Code obligation and an ISO 9001:2015 cl. 10.2 standard, not an institutional preference.

Where a finding amounts to non-compliance, the matter is referred to the JCU AEC Non-compliance Procedure for classification and proportionate response (see Module 8). Where sanctions or remedial conditions have previously been imposed, a targeted PAM review forms part of the conditions of reinstatement and continues until the AEC is satisfied that sustained compliance has been demonstrated.

## 6.5 PI obligations under PAM

- Keep the approved personnel list, training, and competency records current. Only approved personnel may perform approved procedures.
- Keep labelling, monitoring records, and the Schedule 8 register up to date in real time, not in retrospect (and see Module 7 on labelling).
- Allow access during inspections and provide records when asked. Refusal or obstruction is itself a compliance concern.
- Self-report deviations, UAEs, and near-misses on identification, in writing to the AWCO (see Module 5 and Module 8).
- Submit amendments before the change is implemented. Protocol drift is the single most common finding at compliance audit and is itself a non-compliance.
- **GECO reminders.** GECO automatically issues reminder emails in the lead-up to progress reports, final reports, Annual Animal Use Reports and approval expiries, with successive prompts as each due date approaches. These reminders are sent from an external address (noreply@academic.ie) and are frequently filtered to junk or clutter folders; they are useful but should never be relied on as the sole control. For the full notification schedule, the cadence of reminders against each report type, and guidance on building a personal control layer alongside the automated alerts, see Module 11 of the **GECO Training Booklet — GECO Notifications: What You'll Receive, When, and What to Do**.

### Verification, not enforcement

PAM verifies whether what is happening on the ground matches what was approved on paper. It is not, of itself, a sanctioning instrument; sanctions are applied only through the JCU AEC Non-compliance Procedure, with due process and rights of review. PAM activities should feel collaborative; findings should be explainable; corrective actions should make sense. Where they do not, raise it with the AWCO. The annual effectiveness review of the PAM Procedure (per Code cl. 2.1.9) is the formal mechanism for improving it.

# Module 7 — Labelling, facility records, and traceability

**Learning Outcome**

By the end of this module, you will know what tank, enclosure and facility records must show, and why labelling is a compliance issue, not a housekeeping issue.

## 7.1 What the label must show

The information required depends on whether animals are identified individually or at the cage, tank or enclosure level. As a minimum:

- **For all animals, regardless of identification level:** the in-force AEC approval number; the researcher responsible; and, preferably, an emergency contact number for the immediate area.
- **For individually identifiable animals**: **(Ruminants; horses; poultry; fish; rats and mice)** the method of individual identification varies by species — for example, ear tags linked to the National Livestock Identification System (NLIS) for ruminants; ID neck tags and microchips for horses; leg bands for individually-tracked poultry; Elastomer (VIE) or T-bar / dart for fish; and ear notching or ear punching for mice and rats.
  With limited exceptions, each animal must be uniquely and physically identifiable so that individual monitoring (e.g. body weights, clinical observations) can be reliably attributed to that animal over time.
- **For animals identified at the cage, tank or enclosure level: (Ruminants; horses; and poultry)** the number of animals held in the cage, pen or paddock; **(Fish)** the exact or approximate number of animals held, the arrival date, the species, and any relevant comment that help with the identification. Where a researcher occupies an entire room or laboratory, tank-level labelling is not required — a single document carrying the same fields, displayed on or near the door, is acceptable in place of labelling every tank; **(Mice and rats):** animal or cage identification; the number of animals held in the cage with their specific characteristics; and the procedures performed, with dates. Some facilities operate an established card-based system that captures this information — for example, the JCU Bioresources cage card, which records strain, sex, researcher, ethics number, arrival date and either age on arrival (for externally sourced animals) or date of birth (for animals bred in-house), and is reversed at the start of the experiment so that procedures and dates are logged on the same card.

Where a system is in place, follow the local facility practice rather than duplicating it.

Facility records must align with the GECO approval record. The AWCO will cross-check labelling, facility records and GECO records at compliance inspection.

Animal monitoring logs (daily checks, water quality, environmental conditions, clinical observations) must be retained for the period of approval plus the JCU records-retention period.

## 7.2 Why labelling is a compliance issue

- Inspectors — internal and external — use labelling as the first indicator of coverage. Anything labelled with an expired approval number is, on its face, evidence of unauthorised use.
- Where labelling is wrong, the conversation with the regulator is no longer about whether welfare is good (it may be); it is about whether the institution can demonstrate it knows what is held where, under what authority. Labelling discrepancies escalate inspection scrutiny.
- Labelling is also a control on the PI themselves. An expired approval number to identify the project is the prompt that makes a long-running, low-salience problem visible. Pay attention to the labels in your own facility.

# Module 8 — Non-compliance, self-reporting, and the Sanctions Ladder

**Learning Outcome**
By the end of this module, you will know how a non-compliance is classified at JCU, how severity drives sanctions, and what mitigating and aggravating factors the AEC considers.

## 8.1 How severity is determined

Severity is determined under §7 of the Non-compliance Procedure using a weighted scoring matrix across six considerations: impact on animal welfare (weight 3), intent (weight 2), number of animals affected (weight 2), repetition / pattern (weight 2), duration of breach (weight 1), and transparency / cooperation (weight 1). Each is scored 1 (Minor) to 4 (Critical). The total maps to a tier: Minor (11–19), Moderate (20–27), Serious (28–35), Critical (36–44). Floor rules apply if welfare impact or intent scores 3 or 4.

## 8.2 How sanctions are derived from severity

| Step | Sanction | Default tier alignment |
|---|---|---|
| **1** | Education / guidance | Minor — first-time, self-reported, administrative |
| **2** | Supervised work period | Minor — repeat; or mitigation applicated |
| **3** | Required retraining / competency reassessment | Moderate — skill gap as root cause |
| **4** | Formal written warning (copy to College / Unit) | Moderate — repeat or considerable impact |
| **5** | Suspension of individual project | Serious — while CAPA implemented |
| **6** | Suspension of investigator (all projects) | Serious — repeat; ongoing welfare risk |
| **7** | Withdrawal of AEC approval | Critical — systemic disregard |
| **8** | Referral to Research Integrity (ACRCR 2018) | Any tier — falsification / research misconduct |
| **9** | Referral to DVC-R (EA cl. 50) | Critical — wilful serious misconduct |
| **10** | Termination / referral to QPS | Critical — criminal conduct |

## 8.3 Mitigating and aggravating factors

- **Mitigating —** voluntary self-report before detection (−1 step on the ladder, Minor / Moderate only); prompt acknowledgement and full cooperation; absence of welfare harm; absence of new procedures or species introduced; substantive preparation of corrective action.
- **Aggravating —** prolonged duration of breach; large number of animals affected; pattern of similar breaches by the same PI; repetition after a previous correction; deliberate, reckless, or negligent conduct; concealment or falsification.

## 8.4 Repeat-offender pathway

A second non-compliance of equivalent or greater severity against the same PI within 12 months of a prior finding engages the repeat-offender pathway, which includes: automatic escalation to the full AEC (not Executive); sanction increased by one step on the Sanctions Ladder; automatic referral to the DVC-R under the Enterprise Agreement; mandatory compliance review of all projects held by the PI; and increased PAM frequency under the PAM SOP risk-rating mechanism.

# Quick reference: PI lifecycle responsibilities

*Use the items below as a personal pre-flight checklist. Read in the first person, they describe the obligations every JCU Principal Investigator is expected to discharge across the life of an approval.*

### Lifecycle self-check

☐ I have an in-force AEC approval covering every animal I hold, every procedure I perform, every species I work with, every facility I work in, and every personnel I name — at every moment during the project.

☐ I have recorded the expiry date of every approval on which I am PI in my own calendar, with reminders at 120, 90, 60, 30 and 14 days prior to expiry.

☐ I have lodged the annual report on each in-force approval on its anniversary.

☐ I have made an active pre-expiry decision (close / extend / renew / replace) at the 120-day mark on every approaching expiry — not let the date drift past.

☐ I have secured my co-investigators' declarations and training certificates well before any submission deadline.

☐ My tanks, pens and enclosures are labelled with the in-force AEC approval number; historical labels have been removed or updated.

☐ Where ethics responsibilities were handed to me by a previous PI, I have a written record of the handover and have confirmed expiry dates and renewal triggers.

☐ Where my previous renewal trigger has changed, I have updated my personal pre-expiry control to reflect the new operational reality.

☐ I would self-report a lapse on the same day I discovered it, in writing to the AWCO, regardless of welfare outcome.

☐ I have completed the GECO Training Booklet and this AEC Approval Lifecycle Booklet, and I have confirmed completion with the AWCO.

# Key references and further reading

## Regulatory and Code references


- **NHMRC (2013).** Australian Code for the Care and Use of Animals for Scientific Purposes. 8th edition. National Health and Medical Research Council, Canberra — particularly Clauses 1.1, 2.4.1, 2.4.4, 2.4.9, 2.4.27, and Chapter 3.2 on animal housing and husbandry.
- Animal Care and Protection Act 2001 (Qld), particularly Part 5 (Use of animals for scientific purposes).
- Animal Care and Protection Regulation 2023 (Qld), including biennial use returns and registration obligations.


## Animal welfare science


- **Mellor DJ, Beausoleil NJ, Littlewood KE, et al. (2020).** Five Provisions and Aligned Animal Welfare Aims: A Workable Model for Welfare Assessment. Animals 10(10):1870 — the Five Domains framework, widely used as a contemporary welfare-assessment lens in scientific animal use.
- **World Organisation for Animal Health (WOAH).** Terrestrial Animal Health Code, Chapter 7.1 — Introduction to recommendations for animal welfare. The international welfare framework most commonly applied by regulators.
- **Smith AJ, Clutton RE, Lilley E, Hansen KEA, Brattelid T (2018).** The PREPARE guidelines for planning animal research and testing. Laboratory Animals 52(2):135–141 — planning instrument complementary to ARRIVE.
- **Percie du Sert N, Hurst V, Ahluwalia A, et al. (2020).** The ARRIVE guidelines 2.0: Updated guidelines for reporting animal research. PLOS Biology 18(7):e3000410 — reporting standard for animal research, also useful as a planning aid.


## Quality management and just-culture frameworks


- **ISO 9001:2015.** Quality management systems — Requirements. Clause 10.2 (Nonconformity and corrective action) — the source of the CAPA discipline applied at JCU.
- **21 CFR 820.100.** Quality System Regulation, §820.100 (Corrective and preventive action). Food and Drug Administration — the US regulatory analogue of ISO 9001 cl. 10.2.
- **Reason J (1997).** Managing the Risks of Organizational Accidents. Ashgate — the just-culture and Swiss-cheese-model basis of the JCU procedure's approach to honest error vs reckless or wilful breach.
- **Dekker S (2007).** Just Culture: Balancing Safety and Accountability. Ashgate — extension of Reason for contemporary safety-critical organisations.

- **Ayres I, Braithwaite J (1992).** Responsive Regulation: Transcending the Deregulation Debate. Oxford University Press — the regulatory-theory basis of the JCU Sanctions Ladder (educative response first; escalation only where warranted).


### Root cause analysis methodology


- **Ishikawa K (1968).** Guide to Quality Control. Asian Productivity Organisation — origin of the Ishikawa (fishbone) cause-and-effect diagram used in JCU non-compliance investigations.
- **Ohno T (1988).** Toyota Production System: Beyond Large-Scale Production. Productivity Press — origin of the Five-Whys causation chain.
- **Gano DL (2007).** Apollo Root Cause Analysis: A New Way of Thinking. 3rd edition. Apollonian Publications — contemporary structured RCA methodology applied to investigations.
- **Paradies M, Unger L (2000).** TapRooT: The System for Root Cause Analysis, Problem Investigation, and Proactive Improvement. System Improvements — alternative RCA methodology applied internationally.


### JCU institutional

- JCU AEC Non-compliance Procedure.
- JCU Research and Innovation Services — Animal Research Ethics Application Guide.
- JCU AEC Member Induction Booklet (current edition).
- JCU Code of Conduct and JCU Work Health and Safety Policy.
- JCU Records Management Policy (minimum seven-year retention for AEC and compliance records).

**If in doubt, ask before you act.**

The Ethics Office and the AWCO would rather receive ten precautionary enquiries than one post-hoc non-compliance report. A short email to ethics@jcu.edu.au is always the right answer if you are unsure whether your activity is within approval.