**Scientific procedures and specified animal breeding licence Audit template**

* **Core Module - Institutional responsibilities**

## Audit details:

| Licence name and number: |  |
| --- | --- |
| Licence nominee: |  |
| Nominated animal ethics committee/s: |  |
| Names of personnel providing information / role or title: |  |
| Date(s) of interview:  |  |
| Name of auditor(s):  |  |

## Part A: Checklist to be used at interview:

| Responsibility  | C/CWR/NC | Comment |
| --- | --- | --- |
| Structure (attach organisational chart if possible) |
| Nominated senior member of the institution responsible for overall governance of animal care and use. |  |  |
| Is there a compliance officer? [research integrity, AWO, other?] |  |  |
| Who does the AEC directly report to? |  |  |
| Conflict of interest |  |  |
| Any conflict of interest between AEC and LN?  |  |  |
| Role of veterinarian – clinical management, training, research assistant, policy officer, delegate of AEC?*\*Guideline link – Veterinarians in animal research and teaching*  |  |  |
| Policies and guidelines |  |  |
| Are policies and procedures for the following made available and promoted *Ref part C self-assessment*:* animal care and use
* work health and safety
* confidentiality
* freedom of information legislation
* legal requirements
* conscientious objections (teaching)
* privacy
* commercial-in-confidence considerations
 |  |  |
| Procedures for governance and operation of the AEC? *Ref part C self-assessment* |  |  |
| Guidelines on how AEC assesses personnel competency? *Ref part A self-assessment* |  |  |
| Education and training |
| Are investigators well informed of their responsibilities under the Australian code and their legal responsibilities? What are the modes of information available to researchers?  |  |  |
| Are facility managers and animal carers well informed of their responsibilities under the Australian code and their legal responsibilities? What are the modes of information available to facility managers and animal carers? |  |  |
| Is there induction / refresher training in legal obligations? Is it compulsory? |  |  |
| Is there training in animal handling and basic procedures? |  |  |
| Resources  |
| Resources provided for appropriate education, training, and assessment of competence of investigators, and certification of such competence to the satisfaction of the AEC. |  |  |
| AEC provided with staffing and financial resources* Staffing/administrative support
* Financial and expenses
* Orientation and education
* Post-approval monitoring
 |  |  |
| Is the AEC provided with resources for orientation and education of AEC members? |  |  |
| Is the AEC provided with resources to reimburse out-of-pocket expenses and/or payment of an allowance to AEC members? |  |  |
| Arrangements for provision of veterinary advice & program of veterinary care*\*Guideline link – Veterinarians in animal research and teaching* |  |  |
| Compliance |
| Procedures available for dealing with complaints? *Ref part D self-assessment* |  |  |
| Procedures available for dealing with non-compliance? *Ref part E self-assessment* |  |  |
| Is there a register of breaches of the Australian code?*Ref self-assessment Part 2* |  |  |
| Are mechanisms for response to AEC recommendations for Australian code compliance provided? |  |  |
| Response to previous audit findings? |  |  |
| What are the reporting structures in place to ensure that timely and accurate compliance information is communicated to management and the licence holder? |  |  |
| Annual review of effectiveness of processes regarding complaints and non-compliance? |  |  |
| Annual review of the operation of the AEC? |  |  |
| Institutions that use an AEC established by another institute |
| Is such use based on a formal agreement that has been developed in consultation with the AEC? |  |  |
| Does the agreement include procedures for ensuring that the second institution can meet its responsibilities regarding the AEC? |  |  |
| Does the agreement include procedures for communication between the AEC and the second institution, including governance and reporting? |  |  |
| Does the agreement include an undertaking by the second institution that their investigators and other relevant personnel will abide by the directions of the AEC? |  |  |
| Does the agreement include an undertaking by the second institution to abide by the AEC’s policies and procedures regarding non-compliance? |  |  |
| Does the agreement include the circumstances under which either institution may withdraw from the agreement? |  |  |
| Responsibilities of investigators - collaborations  |
| Do investigators notify the 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?  |  |  |
| Do investigators who plan to use animals in another country obtain approval from their institutional AEC for such use?Do investigators provide the AEC with advice on how the proposed project (in another country) can meet the principles of the Australian code, taking into account compliance with local requirements? |  |  |
| Projects across multiple AECs – Responsibilities of institutions and AECs |
| Does the institution ensure that projects involving investigators from more than one institution, or the care and use of animals at more than one institution, are approved and monitored by the responsible AECs? |  |  |
| Are there procedures developed and implemented to ensure that all parties involved are aware of, and can meet, their respective responsibilities under the requirements of the Australian code |  |  |
| Are there procedures developed and implemented to ensure that a project does not commence before each AEC approves, or the delegate AEC approves (see Clause 2.6.5), activities to be conducted by members of its institution |  |  |
| Are there procedures developed and implemented to ensure that the responsible AECs are aware of all aspects of the proposed use of animals, and consider the cumulative effects on the wellbeing of the animals involved |  |  |
| Are there procedures developed and implemented to ensure that the responsible AECs can inspect the animals so that all phases of the project are monitored, including any animal transport between sites |  |  |
| Are there procedures developed and implemented to ensure that animals will receive appropriate care in all phases of the project, including any animal transport between sites |  |  |
| Are there procedures developed and implemented to ensure that clear communication channels are established between all AECs and all investigators |  |  |
| Special conditions on licence  |
| Compliant with any special conditions on licence? |  |  |

## outcomes

Do the findings of other modules conclude that the following institutional responsibilities are being met?

|  |  |  |
| --- | --- | --- |
| Responsibility  | C/CWR/NC | Comment |
| All activities involving animal care and use comply with the Australian code, through an AEC constituted and functioning according to the Australian code. |  |  |
| Governing principles of the Australian code promoted and adopted in animal care and use to facilitate the application of the 3Rs |  |  |
| Clearly identified person responsible for the animals at any given time to ensure:* animal wellbeing is monitored by competent people at all stages and sites of animal care and use. The scope of day-to-day monitoring must be clearly outlined and communicated to all parties
* appropriate actions are taken in cases of unexpected adverse events and emergencies that require welfare interventions, such as treatment or humane killing of an animal
* disease outbreaks and emergencies, such as fire, power failure and biosafety issues, are promptly detected and effectively managed
 |  |  |
| Appropriate actions are taken when unexpected adverse events and emergencies require welfare interventions. |  |  |
| Practices and procedures for the care and management of animals are based on current best practice. |  |  |
| Animal wellbeing is always monitored by competent people, with a clear outline of the scope of day-to-day monitoring communication to all parties. |  |  |
| Adequate numbers of competent people are employed to care for animals. |  |  |
| Relevant personnel and AEC members are advised of the potential disease hazards and other occupational health and safety issues associated with the care and use of animals. |  |  |
|  AEC |
| Is the AEC provided with the resources required to carry out its responsibilities, and to maintain itself? |  |  |
| Guidelines for animal care and use are developed:* in consultation with the AEC
* approved by the AEC
* implemented and promoted within the institution

*Ref Part A self assessment* |  |  |
| Effectiveness of communication between chair & institution |  |  |
| AEC advice is sought on matters that may affect the welfare of animals used for scientific purposes by the institution?* Animal facilities / adjacent construction
 |  |  |
| Notification to department before change in membership of AEC? |  |  |
| For facilities |
| Adequate resources are provided to the people caring for and using animals. |  |  |
| The care and management of animals is under the direction of competent people with appropriate animal care or veterinary qualifications or experience.*\*Guideline link – Veterinarians in animal research and teaching* |  |  |
| All animal housing, facilities and equipment used for the purpose of the licence comply with mandatory codes. |  |  |
| Facilities kept in good order and repair. |  |  |
| Equipment clean and kept in good order and repair. |  |  |
| For non-compliance |
| AEC concerns regarding non-compliance with the Australian code are addressed. |  |  |