EXTRACT FROM THE ANIMAL USERS'S HANDBOOK – Section 48 and 49

48. RECORD KEEPING REQUIREMENTS

- Investigators and Teachers must have a system for the recording of scientific and animal welfare observations. Use of both Laboratory record books, and Clinical Record Sheets is usually recommended. Breeding information must be recorded and stored.
- Clinical record Sheets are considered equivalent to research data.
- During the experiment, the CRS is to be stored in the animal room.
- At the end of the experiment, the CRS is stored with other laboratory records, and retained for the same period required for research data.
- The CRS and other project and breeding records are to be made available upon request to the AEC for audit and review.

49. RECORD KEEPING REQUIREMENTS ENDORSED BY THE STATE GOVERNMENT REGULATOR (DEW)

Guidelines for record keeping by investigators. This data will be required for the annual report, so it is wise to keep it up to date as the project progresses.

The Code Section 2, Paragraph 2.4.30 – 2.4.33 states:

- Investigators must maintain records of the care and use of animals, and make such records available to the institution, the AEC and authorised external reviewers.
- Investigators must ensure that records of monitoring and assessment of animals are in accordance with Clauses 3.1.21–3.1.22.
- Investigators must ensure that records include:

  (i) the origin/source of the animals and provisions for the animals at the conclusion of their use

  (ii) the number of animals used

  (iii) details of procedures, including dates, substances administered, analgesia and anaesthesia, and any unexpected outcomes

  (iv) the condition of the animal, any adverse impact on animal wellbeing and actions taken as a result

  (v) any additional information requested by the AEC

  (vi) names of people performing the procedures and entering the records

(vii) names and contact details of people responsible for monitoring and emergency incidents.

- When activities involve genetically modified animals, records must include:

  (i) the number of animals used for the creation and maintenance of genetically modified animals

  (ii) the lineage and health status of the animals.

In general, the recording of information in a workbook should allow use of an animal to be traced from acquisition to the conclusion of the approved protocol. The following represents guidelines and is not an exhaustive list. The principles outlined in the Code (above) represent the minimum standards.

Records should be maintained by individual researchers on administrative procedures necessary for the project:

- Animal Ethics Committee approval number, date and duration of approval.
- Records relating to adherence to specific conditions which AEC may include in project approval.
- Running tally of animal use against numbers approved.
- Reports of any adverse outcomes

Monitoring of individual animals' passage through the protocol must be demonstrated, so each animal must be identified and have the following records attributable to it:

- Full ID (species, strain, sex, age, ID)
- Date of acquisition and source
- Place of housing
- Monitoring of health and welfare of the animal over the duration of the experiment and personnel involved (e.g., records of daily monitoring, completed checklists).
- Place and date of procedure
- Identification of part of approved project conducted on each date (e.g., weighing, administration of agents, surgery, killing)
- Details of procedure being conducted (e.g., dose rates, volumes of agents administered, surgical technique) and personnel involved.
- Details of anaesthesia if used: dose, administration, analgesia and monitoring and personnel involved.
- Records of recovery post-procedure +/- post-anaesthesia, including record of response to adverse events, predicted or not. Name(s) of personnel monitoring.
- Culling/ euthanasia records including reason, method and nomination of personnel involved.

The Code Section 3, Paragraph 3.1.9 states: Investigators and teachers must ensure that records of the use and monitoring of animals used for scientific purposes are maintained. Under a particular AEC approval, records should include the origin and fate of issued animals, how animal welfare was assessed, any unexpected negative impact on animal wellbeing and notation of procedures. The AEC should advise investigators and teachers of any additional information to be recorded. These records should be available for audit by the institution and authorized external reviewers.

Evidence of preparation for adverse events and adherence to Standard Operating Procedures (SOPs):

- Reference to any specific SOP.
- Specification of adverse events and procedures put in place to manage these events.