Animal Use in Research, Testing and Teaching in New Zealand

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Training manual

2022

Outline of Study Manual

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- Section 1:
  - Legislation & compliance
  - The application process
- Section 2:
  - Animal welfare management
- Section 3:
  - Drugs use in research, testing and teaching (RTT)

Use of animals for RTT in NZ is controlled by legislation & guidelines

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- Animal Welfare Act 1999
- University of Canterbury Code of Ethical Conduct for the Use of Animals
- Codes and guidelines of animal welfare

Controls continued

- MAF Biosecurity Authority Standard 154.03.3
  - Covers the use of genetically modified animals
- MPI Good Practice Guide for use of animals in RTT. Copy available from: https://www.mpi.govt.nz/animals/animal-welfare/animals-research-testing-teaching/
- University of Canterbury policies for RTT:
  - This training module
  - Requirement to track animal numbers used in RTT
  - Training by University Vet

The Animal Welfare Act 1999

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- Applies to private individuals, research institutions, animal shelters, circus operators. . . . everyone in NZ
- Designed to prevent ill-treatment and inadequate care of animals
- Obligations on owners, students, staff and people in charge of animals:
  - To meet the physical, health and behavioural needs of animals
  - To provide treatment to alleviate unnecessary pain and distress

- Please download and read the Act: https://www.legislation.govt.nz/act/public/1999/0142/latest/whole.html

Research scientists are given a special privilege in New Zealand

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- The Animal Welfare Act gives special privileges to scientists (that are not given to the general public) for animal use

privilege |ˈpriv(ə)lij| noun a special right, advantage, or immunity granted or available only to a particular person or group of people

- The limits and controls on these privileges are managed through the Animal Ethics Committee (AEC) system

Animal use in research is a privilege, not a scientist's birthright:

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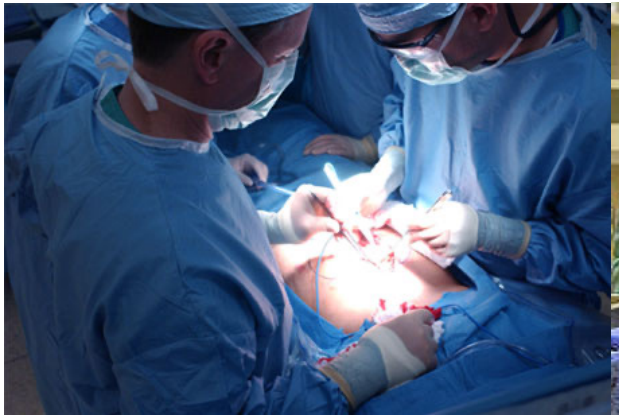

As medical qualification is required for human surgery…..

And veterinary qualification is required for animal surgery…

….so too is University of Canterbury AEC approval required for animal research

Special privileges for scientists in NZ

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NZ scientists are allowed to perform vivisection & manipulations on live animals without a veterinary qualification, but only if:

1. Findings advance knowledge of human health, animal welfare and/or productivity, or ecosystems
2. Benefits outweigh the harm to animals
3. Results benefit welfare of great apes (non-human primates requires special approval before they can be used for RTT in NZ)
4. Procedures approved by properly constituted Animal Ethics Committee
5. Training and oversight by Vet may be required for some protocols

The Animal Welfare Act (AWA) 1999

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- Promotes "The 3 Rs" (more on this later)
- Requires the University has a Code of Ethical Conduct (CEC)
- Requires the University has an Animal Ethics Committee (AEC) to oversee the use of animals in RTT
- Establishes "independent audits" of the AEC every 5 years
- Establishes 2 committees to advise the Minister of Primary Industry (MPI)
  - NAWAC: National Animal Welfare Advisory Committee
  - NAEAC: National Animal Ethics Advisory Committee

National Animal Ethics Advisory Committee

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- Reviews institutional Codes of Ethical Conduct (UC was reviewed in 2022)
- Has responsibility for & oversees the independent audits
- Provides advice/consultation services for institutional AECs

The University of Canterbury is required to ensure use of animals for RTT complies with all relevant legislation (and thus ensures that you, as a user of animals, also comply with the legislation)

The Principles of Humane Experimental Technique (The 3 R's)

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- William S. Russell & Rex L. Burch proposed the 3 R's in 1959*
  1) Reduction of numbers to minimum necessary
  2) Refinement of techniques to minimise harm
  3) Replace animals by non-sentient or non-living alternatives

*Burch WMA & Burch RL. 1959. The principles of humane experimental technique. Methuen & Co., London (PDF can be found on-line to download for free)

The 3 R's at Canterbury

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- Applications to the UC AEC should include clear statements on the reduction, replacement and refinement strategies that were considered in your proposed use of animals
- Guidance is provided by AEC for those who have not experience with the 3 R's concept
- Applicants are to use appropriate options in their proposed use of animals that follows the 3 R's, whenever possible

The AWA requires a Code of Ethical Conduct

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- Every organisation in New Zealand using animals in RTT must have an approved Code of Ethical Conduct (CEC)
  - Approval for a CEC is given by Director of MPI
  - Code is a license to operate (i.e., for AEC to consider applications for RTT)
  - Codes are valid for 5 years
  - Codes specify how animals will be used & monitored in RTT
  - Our Code is available from the AEC secretary

Who is on the AEC at the University of Canterbury?

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The UC AEC has at least 6 members:

- 1 external member from the NZ Vet Association
- 1 external member from the SPCA
- 1 external member from the Canterbury Regional Council
- Vice Chancellor's representative who acts as Chair of AEC
- 2 UC academics capable of evaluating applicant qualifications and scientific merit of proposal (Chair is also a scientist)
- The 3 external members provide robust independent review of research applications. This is a unique feature of the NZ animal ethics system

Independent Reviews of use of animals at UC

- Code holders and their AECs are audited at regular intervals
- Audits used to check compliance with the Act and with their Code of Ethical Conduct
- University of Canterbury AEC is reviewed every 5 years
- The last review took place in 2022

Key definitions in the Animal Welfare Act 1999

The AWA defines the following key terms that will help you decide if you need to obtain approval from the AEC for your use of animals in RTT:

- Animal
- Manipulation
- Physical, health and behavioural needs
- Research, testing or teaching

These terms are defined on the slides that follow

"Animal" defined as:

Only the following organisms are defined as an "animal" under the AWA:

- Any live mammal, bird, reptile, amphibian, fish, octopus, squid, crab, lobster, or crayfish
- Any fetus or pre-hatched young of mammals, birds or reptiles in the last half of gestation or development, including marsupial pouch young

Under the AWA I am not an animal

When are fetal animals defined as an "animal" under the AWA?

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Fetal mice at day 5 of gestation and younger are not counted or reported as animals under the AWA

- Gestation in mice is approximately 19 days

Fetal rats at day 16 of gestation and older are counted and reported as animals

- Gestation in rats is approximately 21 days

What is a "Manipulation" as defined in the AWA?

A manipulation is any interference with the normal physiological, behavioural or anatomical integrity of the animal by deliberately:

- Exposing it to any parasite, micro-organism, drug, chemical, biological product, radiation, electrical stimulation or environmental condition or enforced activity, restraint, nutrition, surgical intervention, or
- Depriving it of usual care

If you are unsure if your animal is an 'animal' as defined under the AWA, check with the AEC as they will be happy to provide you with guidance.

What is the definition of "Physical health and behavioural needs"

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The following define physical health & behavioural needs of an animal:

- Provision of proper and sufficient food & water
- Provision of adequate shelter
- Opportunity for animals to display normal patterns of behaviour
- Physical handling by researcher that minimises pain and distress of the animal
- Protection from and rapid diagnosis of any significant injury or disease

Providing opportunity to display normal patterns of behaviour

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Examples for holding rodents in cages:

- Cages should allow animals to stand upright
- Cages should provide resting platforms
- Animals should be able to exercise

The exact requirements will differ with other species (e.g. fish) but the general principles should be followed in housing any animal

Rapid diagnosis of any significant injury or disease

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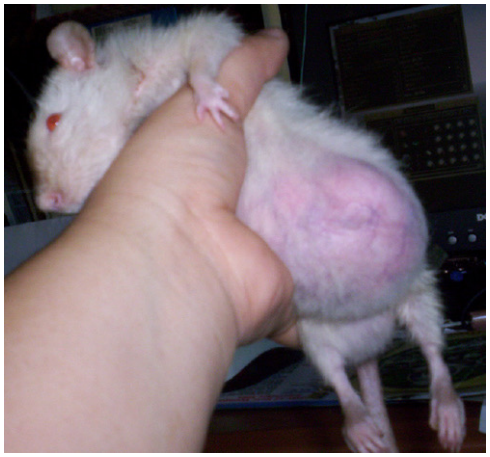
Example of a problem:

- Tumour on rat
- Self mutilation due to neuropathy
- Tail gangrene



- In all cases prompt veterinary attention is required: it is a requirement that researchers ensure any health problems or injuries in their animals are attended to as soon as possible
- UC has appointed a Vet who can be consulted if you have any concerns about the welfare of your animals.

"Research, testing & teaching" is defined as:

Any manipulation of an animal for the purpose of:

- Any investigative, experimental, diagnostic, toxicity or potency testing work
- Any production of antisera or other biological product
- Teaching

Use of animals at UC is almost entirely for the purposes of either teaching or research (we do not test commercial products)

Is your proposed use of animals subject to the AWA Act?

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Do you need to apply to the AEC? Ask yourself the following questions:

- Is it an animal as defined in the Act?
- Is a manipulation being performed?
- Is the purpose of the manipulation covered by the research, testing or teaching definition?
- If YES to all 3, AEC approval is required
- If NO to all, AEC approval is not required
- If uncertain, contact Animal Ethics Committee for advice

Collection of statistics on animal use

Anyone granted approval to use animals in RTT by the AEC is required to provide end of study reporting of:

- Species and numbers used
- Severity of manipulation
- Purpose of study

National animal use data published annually by NAEAC

If you do not provide the AEC with this information, you will be barred from all future use of animals in RTT

NAEAC Annual Report 2020

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A total of 245,522 animals used for RTT in 2020

- 100,834 animals used by universities in NZ

Across the country, the most commonly reported species were fish (56,045), mice (48,993), production animals such as cattle and sheep (94,297) and rodents/rabbits (58,899)

You can download the full report from:

https://www.mpi.govt.nz/animals/animal-welfare/animals-research-testing-teaching/statistics-on-the-use-of-animals-in-research-testing-and-teaching/

NAEAC Annual Report 2020

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Purpose of animals used in 2020

- 30.3% for basic biological research
- 24.9% for animal husbandry
- 10.3% for teaching
- 5.9% for medical research
- 14.1% for veterinary research
- 6.8% for species conservation & environmental management
- 7.1% for testing

International statistics on animal use in RTT

- UK (2020): 2.88 million procedures
- Victoria, Australia (2019): 3,294,755
- European Union (2018) 12,093,096
- Canada (2020): 5,067,778

Codes & Guidelines for Animal Welfare

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Any use of animals in RTT must follow an approved code for animal welfare that:

- Establishes minimum standards of care
- Includes recommendations on best practice

Codes can be drafted by any industry or organisation

- Codes approved by NAWAC and the Minister
- Codes subject to review so researchers using animals in RTT need to keep up to date in latest developments

Codes for some types of animals can be found at: https://www.mpi.govt.nz/animals/animal-welfare/codes/all-animal-welfare-codes/

Some jurisdictional gaps in the legislation

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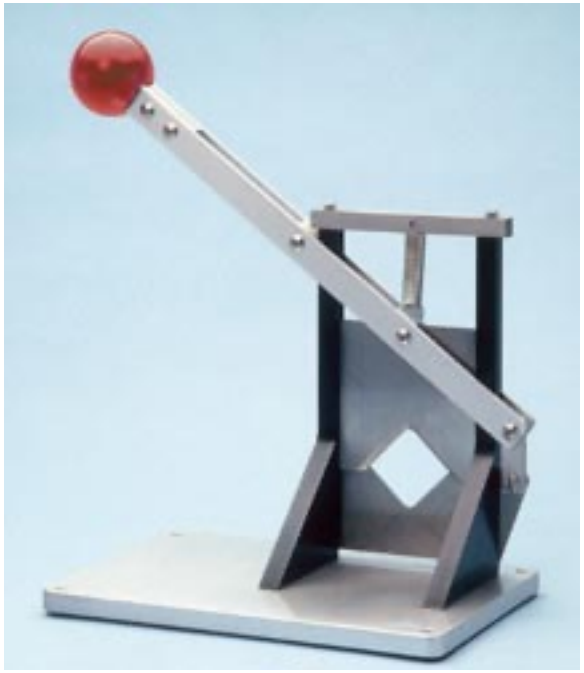
Some activities "fall between the cracks"

- Manipulations on "non-animals" such as oocytes, blastocysts, embryos; has potential for harm in adult animal*
- Microinjection of fish eggs does not require AEC approval*
- Until 2015, killing animals was not a manipulation according to the Animal Welfare Act!

* Note: UC still requires researchers to obtain approval if obtaining such non-animals requires manipulation of the adults

Killing was not a manipulation?

- Killing is the ultimate "anatomical interference"
- Until 2015, the AWA was a contradiction in this matter
- Eventually attempts by NAEAC to change the AWA were successful and AEC approval is now needed to kill an animal
- **Note: University of Canterbury has always required AEC approval for animal euthanasia (even before 2015)**



The Animal Welfare Act 1999 Penalties for Conviction

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There are penalties for breaking the AWA:

- For carrying out studies without AEC approval
- For failing to comply with conditions set by the AEC
  - Individuals fined $25,000 and/or 6 months imprisonment
  - Corporations fined $125,000

Breaking the law will also result in the loss of all privileges to use animals in RTT as either a student or employee of the UC

Convictions under the Animal Welfare Act 1999

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- There have been several convictions under this Act since its implementation
  - Inhumane treatment of horses
  - Inhumane treatment of sheep
  - Dog dragged behind a vehicle
  - Administration of a new veterinary medicine to a flock of sheep without a Code of Ethical Conduct

Application Process at the University of Canterbury

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- Forms can be obtained from the Animal Ethics Committee secretary
- Students: please ask your supervisor to obtain the application forms for you
- Make sure you have the latest version of the application form
- Please read the instructions first
- Fill out the form and submit to AEC secretary:

  animal-ethics@canterbury.ac.nz

Note: in early 2023 all AEC applications will move to a new entirely on-line format. Please check with secretary for latest update.

Application forms

- There are separate applications for: (1) use of animals in research and (2) for use of animals in teaching
- Please ensure you obtain the correct form before submitting it to the AEC secretary
- Applications for use of animals in teaching must include a copy of the lab instructions and/or handout given to the students
- Undergraduates must also receive training in their responsibilities under the AWA (if you are a lecturer that uses animals in teaching, contact AEC directly for advice on this matter)

Who may apply for AEC approval?

- Academics, postdoctoral fellows and senior technical staff employed by the University can apply to the AEC to use animals in RTT
- Graduate students can apply as a Principal Investigator but must have a named supervisor on the application form
- Scientists outside the University cannot apply to the UC AEC as currently we do not have any formal parenting agreements between UC and outside organisations or industry

Status of students in the AEC application process

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- Students at UC may participate in drafting AEC applications & submit an application but the project must be supervised by a UC academic
- All animal use by students must be supervised by the academic staff member who has signatory responsibility
- Students cannot modify AEC applications without approval from their supervisors; any requests for modifications to approved protocols must be made in writing to the AEC through the submission of an amendment application

What criteria does the AEC use when assessing your application?

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- What are the scientific or teaching objectives?
- What is the harm/distress to animals & how is this managed?
- Will experimental design will meet study objectives?
- Appropriate choice of species & minimum number of animals
- Animal welfare measures taken before and after manipulations?
- Suitably qualified personnel?
- Any duplication of previous work?
- Any multiple use of animals?
- Any commitment to ensure findings are used, promoted or published?

How many animals will I be allowed to use?

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- The policy of the AEC is to ensure the minimum numbers of animals are used but using too few animals also raises concerns as this prevents robust conclusions being drawn and animals may have suffered for no tangible outcome

- In your application to the AEC please provide justification for the number of animal you wish to use

- Although the AEC realises it can be difficult to determine exact samples sizes required, the use of power tests and the results of similar studies should be used to provide evidence to the AEC that the number requested wasn't just "pulled out of a hat"

Research design

- In your application make it clear what will happen to the animals in the course of your research; describe your research design, and ensure that you clearly outline what the animals will experience
- The AEC will want to know whether the subject numbers proposed are adequate to achieve your research goals, but not more than is necessary; where several experiments are involved, make sure you explain what these are and how they fit into your overall design
- In keeping with the 3 R's, maximise what you can learn from each animal, and where possible, reuse animals when this does not compromise the experimental design or animal welfare

How am I informed of AEC decisions?

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- Committee decisions are e-mailed to the applicant within a few days of approval (usually the same day)
- AEC decisions are:
  - Approval without qualifications
  - Approved with provisos
  - Deferred for clarification or further information
  - Declined
- Approvals are given for the length of study, but the maximum approval time is 3 years. If you study extends for more than 3 years, you will need to re-apply for further approval.

Animal ethics exam

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- Every applicant must successfully complete an exam on the training module
- A successful exam provides us with evidence that you understand your obligations as a user of animals for research or teaching in New Zealand
- If you have not completed the exam successfully you cannot obtain an approval to use animals
- Unsuccessful candidate may sit the exam again, after they have reviewed the training module
- Candidates must obtain a score of 80% or higher to pass the exam

To change an approved protocol

- Once a project is underway it may become necessary to change or add a procedure, use additional animals, extend the end of the study, change name of personnel, etc.
- All such changes must be approved by the AEC
- To change or amend a previously approved protocol, submit the amendment application form (obtained from AEC secretary)
- Simple changes may be approved quickly but more substantial changes require more amendments to the original application
- There is a maximum of 3 amendments allowed per approved application. If you require further amendments you must resubmit the entire project again for reassessment.

URGENT applications!

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- The AEC endeavours to process applications as quickly as possible but it may take several weeks for feedback to be received and assessed (AEC members are given 2 weeks to provide feedback)
- Questions raised by the AEC can delay the processing of an application thus it is useful to prepare application carefully in the first place (e.g. 3 R's, etc.)
- Urgent requests may be considered due to circumstances beyond your control; failure on your part to allow enough time is not a good enough reason!

Why should I comply?

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- Compliance is in the best interests of the scientist/researcher because:
  - You are breaking the law otherwise
  - Animal use privileges can be withdrawn
  - AEC approval is a license to use animals
  - AEC approval confirms and supports the scientist's research, especially if challenged by the public or the media
  - Most journals require the authors provide evidence that they work complied with local regulations before they will publish your research: the AEC provides you with the evidence that your work complied with the AWA

Consequences of non-compliance

Non-compliance can lead to:

- Compromised animal welfare
- Unreliable or inaccurate research data
- Approval to use animals is withdrawn
- Scientific reputation is damaged
- Institutional reputation is compromised
- Fines and/or imprisonment

The AEC -- Principal Investigator (PI) relationship

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- The relationship between the PI and AEC is based upon trust
- The PI's best advocate is the AEC
- The AEC's role is to confirm compliance for the institution and for the Investigator
- AEC support for Investigators is promoted when it is kept informed of any changes to procedures, sample sizes or dates of animal use

The AEC -- Investigator relationship

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- The AEC will defend your approved protocols against public challenge
- Hence the protocol supplied by the investigator must include details sufficient to build a credible defence
- AEC queries are not a challenge to your competence, but a strategy to document and confirm your expertise to carry out the project
- If you do not presently have the skills needed for your project (e.g. surgical skills), there are options for obtaining the training and support from the University Vet

The AEC -- Investigator relationship

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Would your research pass the "TV interview" test?

- The public has a right to question the use of animals in RTT
- AEC will defend approved protocols but requires a strategy to document and confirm your expertise, and the careful ethical consideration that you put into your work
- Your application to the AEC provides the information we need to determine if your protocols will stand up to challenge

The Official Information Act 1982

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- The university is subject to LGOIM Act 1987 & all AEC documents may have to be released to the public
- Every year the UC receives several requests under the LGOIM to release copies of applications, emails, and all other paperwork or correspondence associated with AEC approvals
- Exceptions include protection of trade secrets or intellectual property, and where safety of personnel is compromised
- Applications and all communication to the AEC should be written as if they will become public documents

The Animal Rights movement in NZ

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- There is an active and growing Animal Rights movement in New Zealand
- This can result in some costs to process requests on use of animals under the Official Information Act, but they and other members of the public do have a legal right to know how animals are used at UC
- However, should you feel threatened because of the legal use of animals in your position at the UC, immediately let the AEC know. The NZ Police Threat Assessment Unit is responsible for monitoring criminal activity related to Animal Rights movement and will be informed.

Site visits and monitoring by AEC

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- Site visits by the AEC are part of normal monitoring procedures
- They allow AEC to meet researchers, observe manipulations, confirm compliance with protocols & help with understanding of new protocols proposed by researchers
- Visits are designed to be supportive & helpful, not punitive
- Site visits are scheduled in advance with the PI, and PI is normally present during a visit
- Any recommendations are discussed first with the PI at the end of the visit; formal reports may be given to PI & HoD

Site visits and monitoring by AEC

Additional monitoring includes:

- AEC tour of all animal facilities every 6 months
- Visits by members of AEC in response to request by any PI to investigate welfare concerns
- Site visits can be made unannounced to ensure compliance with approvals
- Clinical examination of animals can be conducted as part of routine care and monitoring by University Veterinarian

End of study reporting

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At the end of the project you are required to fill in a final report.

- Final report form is available from AEC secretary
- The report summarises the key findings from your study (the AEC is interested in what you discovered)
- The report provides a summary of the total number of animals used compared to that approved (note: you cannot use more animals than approved without first obtaining approval by an amendment application)
- Failure to submit a final report will prevent you from obtaining any future approvals

Any questions?

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- If you have any questions regarding the application process, please do not hesitate to conduct the AEC for advice:

animal-ethics@canterbury.ac.nz

The next section in this module examines Animal Welfare Management

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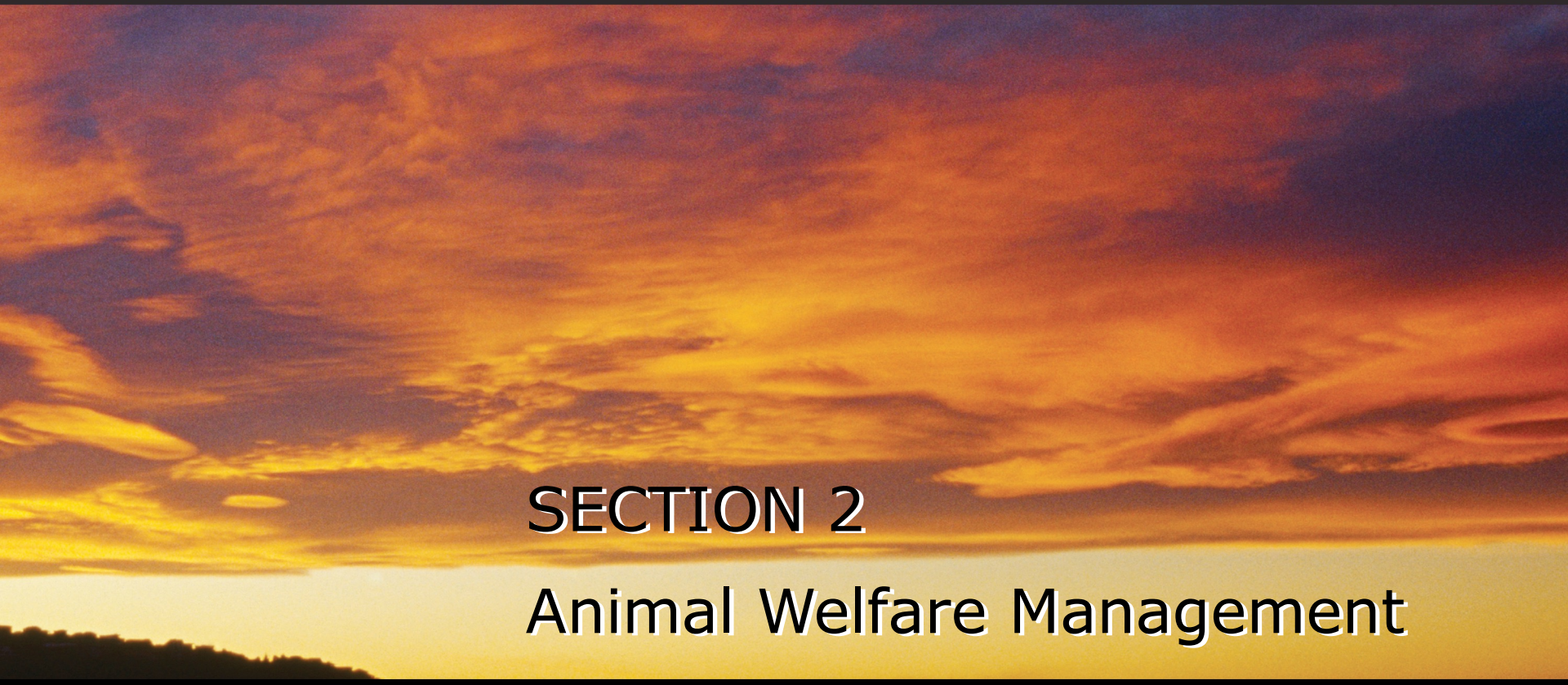

SECTION 2

Animal Welfare Management

All personnel using animals are expected:

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- To have a working knowledge of the protocols for which they have obtained approval
- To comply with the approved protocols as described in their approved application
- To recognise any deviation from the protocols and ensure modifications are first approved
- To have the necessary knowledge & technical skills to perform the manipulations or, if these are inadequate, to then:
  - acquire the skills & knowledge as required or
  - obtain the services of appropriately trained personnel to carry out the manipulations on their behalf

Technical competency is expected by the AEC

- The AEC does not train researchers in the specific protocols they plan to use; it is up to applicants to obtain appropriate training and provide evidence to the AEC they have technical competency
- Competence should be gained by training under supervision:
  - To learn new skills or up-skill previous experience
  - To ensure best practice procedures used

- The University Vet is available to provide training and oversight of surgical protocols

Technical competency is expected by the AEC

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Examples of technical competency:

- Proper animal handling
- Correct drug administration
- Blood sampling
- Use of aseptic procedures
- Surgical procedures, including anaesthetics
- Animal monitoring & post-operative pain management
- Euthanasia methods

Animal Welfare Management

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Management of animal welfare involves:

- Considering the animal's point of view
- Humane endpoints for the protocols
- Monitoring of animal responses and health
- Supportive therapy when required
- Ensuring appropriate veterinary care when needed

The animal's point of view

Imagine yourself in jail as the research subject:

- You have no control over your environment or welfare
- How would you wish be to treated?

The animal's point of view

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1. Provide trained staff to care for me
2. Provide cages which reduce boredom & frustration
3. Be sure you are competent
4. Be sure I am competent
5. Reward me during my training
6. Provide pain relief when necessary
7. Do not let me linger; agree on endpoints
8. Provide trained staff to perform humane euthanasia
9. Obtain maximum scientific information from me
10. Ask yourself: "is it necessary to use me at all?"

Life in a cage

- When an animal cannot move in a cage to obtain food and water, there is a major problem
- Housing facilities for any animal must not only provide the essentials for living (food, water, shelter), but space to move, and to allow normal behaviour
- Deviations from humane care (e.g. maintaining animals below optimal body weight to enhance training) must be first approved by the AEC

Humane endpoints

Your study must have an endpoint:

- Time limit to a proposed manipulation (e.g. response of animals at end of 6 week period to a treatment)
- Death as the endpoint (e.g. lifespan of animals is assessed in response to a drug treatment)
- Humane endpoint (e.g. animals are euthanised when certain criteria of experiment are meet)

The endpoint is not when you carry on with your experiment until you get the result you want. There must be agreed beforehand limits on the extent and duration of any manipulation and these must be approved by the AEC.

Euthanasia

- In some situations animals must be euthanised as an endpoint of an experiment (e.g. to obtain tissue samples for analysis)
- Euthanasia may also be necessary during routine maintenance if:
  - Weight loss >10% over 24 h
  - Clinical signs such as inability to move, self mutilation, hypothermia, diarrhoea, convulsions, etc.
  - An animal reacts in an unexpected way to a manipulation and there is no sign of recovery in a reasonable time

Researchers must have a plan to deal with euthanasia, even in studies where it is unlikely to be used or needed

Does you study cause adverse effects?

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- Protocols that lead to pain, haemorrhage, oedema, weight loss, anorexia, wound infection and/or self mutilation must be dealt with immediately
- Personnel must be familiar with any potential adverse effects and have a plan to manage them
- It is up to the applicant to convince the AEC you have the expertise to recognise such adverse effects and you have a plan to deal with them
- If in doubt, seek help

Monitoring your animal's welfare

Keep records to monitor you animal's welfare:

Observe animal before & after manipulation and record:

- Body weight, coat condition & state of hydration
- Fluid intake
- Respiration pattern; colour of skin, etc.
- Behaviour and locomotion patterns

The exact criteria and frequency of monitoring will depend on species, but it is important to keep written records to quickly identify (and remedy) potential problems

The AEC may ask to see your records on how you have monitored your animal's welfare

Post-operative support

Animals subject to surgical procedures require post-operative support:

- Control of pain with analgesics, NSAIDS and/or euthanasia
- Administration of fluids to maintain hydration
- Maintain body temperature
- Prevent trauma by other animals
- Promote rapid recovery

It is up to researchers to ensure they have adequate training. You will need to provide this assurance to the AEC.

Analgesics

Animals subject to surgical procedures may require pain control:

- Anaesthetics (control of pain during surgery) are not the same as analgesics (control of pain after surgery)
- AEC policy requires analgesics to be routinely administered to all but minor surgery
- Withholding analgesics must be justified to AEC
- Contact the University Veterinarian for advice and training on managing pain control in your animals

Prevention of trauma by other animals

Animals subject to surgical procedures must also be protected from trauma by other animals:

- Animals may need to be left to recover in individual cages
- Surgical wounds attract attention of cage-mates and may be subject to attack
- Breakage of wounds by other animals can result in extreme pain and suffering and must be dealt with immediately
- Regular post-operative monitoring is required to ensure recovery

Learn to recognise a sick animal

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What does a sick animal look like?

- Animal not maintaining personal hygiene (e.g. matted hair)
- Coughing, sneezing, nasal discharges
- Discharges from eyes, swelling of eyes
- Skin lesions
- Diarrhoea
- Inactivity and lack of responsiveness

Learn to recognise a sick animal

What does a sick animal look like?

- Dehydration evident through skin turgor test (animal's skin gently pulled up and released; in dehydrated animals the skin is slow to return to its normal position)

A healthy animal is typically **B.A.R. (bright, alert and responsive)**, is well-groomed, has no discharges & skin returns to normal quickly during a turgor test

Animal welfare

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- It is your responsibility to know your animal and to ensure its welfare
- If you are unsure about any aspect of maintaining the welfare of your animals, you must seek help (either from your supervisor, other academics with the skills and/or the University Vet)
- The role of the AEC is not to provide direct training in animal welfare but to ensure that all personnel using animals in RTT have adequate training
- Maltreatment of animals or failure to provide for the welfare of animals may result in the loss of your privilege to use animals in RTT

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SECTION 3

Drugs used in RTT:

Management of registered veterinary and human medicines in animals at the University of Canterbury

Registered drugs & medicines

- If you plan to use any registered veterinary drug or human medicine in RTT you are subject to additional rules governing their use
- Registered drugs are controlled substances and are thus subject to a series of strict guidelines governing their purchase, use and disposal
- If you plan to use registered drugs for RTT you will be required to submit an IDAO (Institutional Drug Administration Order) form with your animal ethics application

Definitions & Terms

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The following will be covered in this section:

- Prescription Animal Remedy (PAR)
- Agricultural Compounds and Veterinary Medicines Act 1997 (ACVM)
- Drug Control Officer (DCO)
- Controlled Drug Register (CDR)
- Institutional Drug Administration Order (IDAO)
- Institutional Operational Plan (IOP)

What is a Prescription Animal Remedy (PAR)

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- PARs are animal remedies declared by the Director-General to be as such and are under the direct or indirect control of a veterinary surgeon

- PARs are divided into 3 classes:
  - Class I (prescribed by a vet)
  - Class II (used in the presence of a vet)
  - Class III (used only by a vet)

Drug controls in New Zealand

- Drug use in RTT is controlled by the ACVM Act 1997
- A registered veterinarian must provide written prescriptions for all drugs used in RTT on animals at the University of Canterbury
- The University of Canterbury has appointed a vet to assist in the prescription and use of drugs
- Researchers must comply with a Code of Practise governing drug control

The ACVM Act 1997

"…no prescription animal remedy may be administered to, or prescribed or dispensed in respect of, an animal except following a veterinary consultation in respect of that animal"

Section 98 (2)

What is the purpose of the ACVM Act 1997?

Prevention or management of risks associated with the use of agricultural compounds and vet medicines in animals, specifically:

- Risks to trade in primary produce
- Risks to animal welfare
- Risks to agricultural security
- Risks to domestic food safety

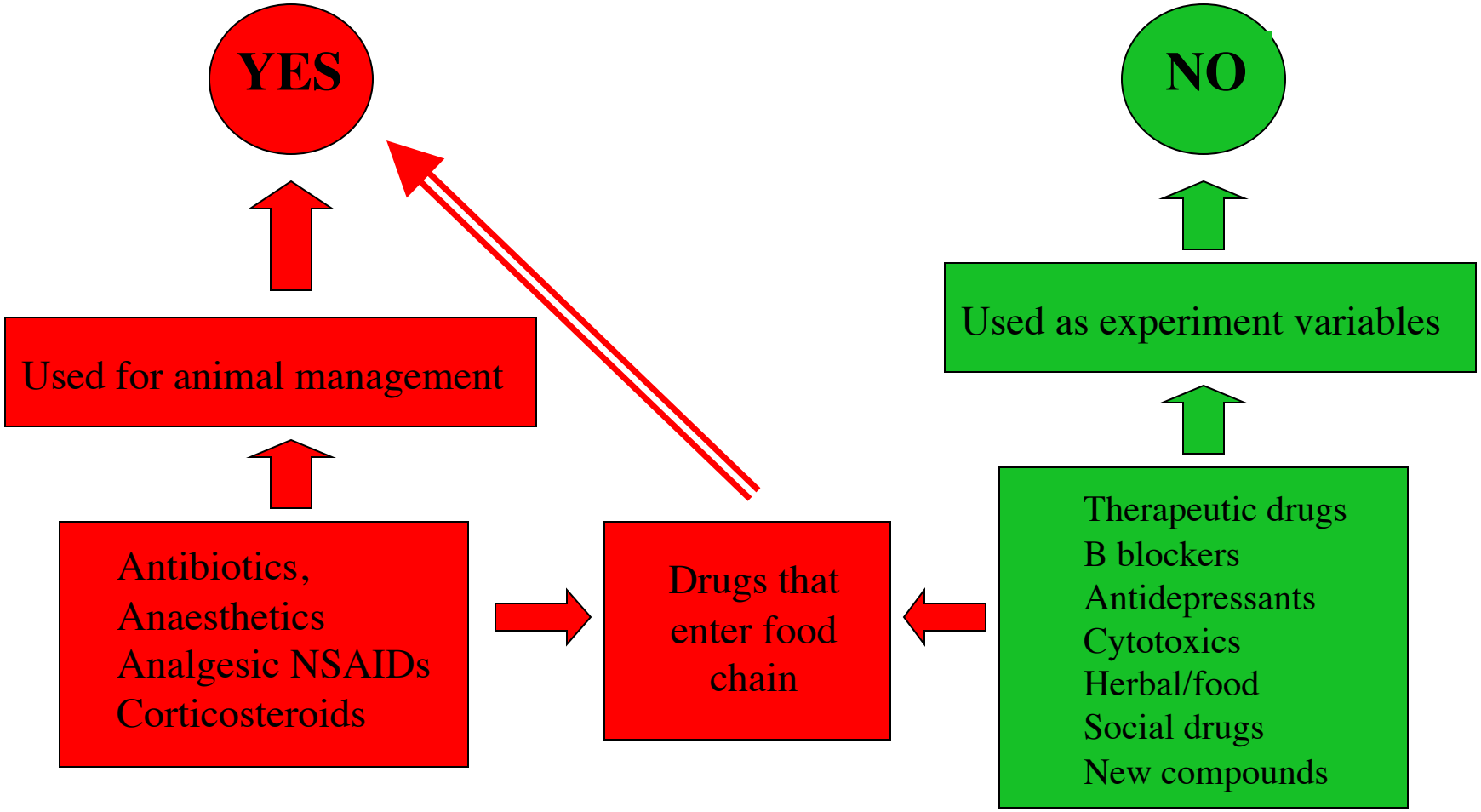
What drugs are involved?

Any product introduced into an animal:

- For the purpose of the management of that animal (as opposed to products used as experimental variables, e.g. hypotensive agents used in a cardiovascular study)
- That will enter the food chain

Most lab animals are unlikely to enter the food chain, but researchers that study wild animals and subject them to a controlled drug (e.g. anaesthetising fish and then releasing them back into the water) must ensure that this animal is not at risk of entering the human food chain (i.e., subsequently caught and eaten by a human while the drug is still present)

If endpoint in this graph is yes, then need IDAO



Institutional Operational Plan (IOP)

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The UC IOP covers:

- Purpose
- Assessment of PAR requirements
- Institutional Drug Admin Orders
- Purchase, dispensing and security of drugs
- Destruction of expired drugs
- Audits of drug controls
- Management of non-compliance
- Provision of training in the use of PARs
- Management of potential food chain contamination
- PARs used in animals released to the wild
- Animal welfare

Prescriptions required under the ACVM Act

- Standard veterinary prescriptions are not sufficient
- University Veterinarian must fill out prescription that includes the following 10 requirements:
  1) Purpose of drug use, aims of trial, linkage with AEC number
  2) Details of the dose rate, route, and frequency of administration
  3) Details of species, age, sex & condition of animal
  4) Details of the training and competence of named personnel
  5) All equipment necessary for medicine administration

Continued next slide..

Prescriptions, continued

6) Management of risks to food chain animals
7) Drug control, security and reconciliation by use of a Controlled Drugs Register
8) Expected treatment outcomes
9) Adverse events
10) Unexpected treatment outcomes

Compared to the usual veterinary prescription, these involve a large amount of paperwork for the University Vet

Compliance with code

- Failure to comply with Code may result in prosecution under the ACVM Act
- Personal fines range from $5,000 to $30,000
- Corporations can be fined from $75,000 to $150,000
- Employers, directors and officers of bodies corporate may also be liable

Drug Control Officers

Drug Control Officers (DCO) have been appointed in both Biology and Psychology

The role of the DCO in each department is to:

- Facilitate and assist users of controlled drugs
- Monitor drug records
- Monitor drug security
- Report regularly to the veterinarian to confirm compliance with policies and to report any non-compliance
- Follow the Institutional Operational Plan

Drug security & record keeping

Drug security and record keeping are supervised by each department's DCO

Drug security is maintained by the installation of drug safes in research laboratories

Record keeping is maintained by a Controlled Drugs Register (CDR)

Controlled Drug Register

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A controlled drug register (CDR) contains:

- One page per drug
- Date of medicine usage
- Initials of authorised user
- Reasons for use
- AEC protocol number
- IDAO number
- Reconciliation of drugs used and/or on hand

A CDR must be completed at the end of each day or at the end of each drug use (when drugs are used infrequently)

Audit requirements of DCO

- The Drug Control Officer is required to undergo an audit once every 2 months on a departmental basis and once every 6 months on an institutional basis

- The principal investigator using controlled drugs must ensure that audits are completed as required

Training requirements for use of controlled drugs

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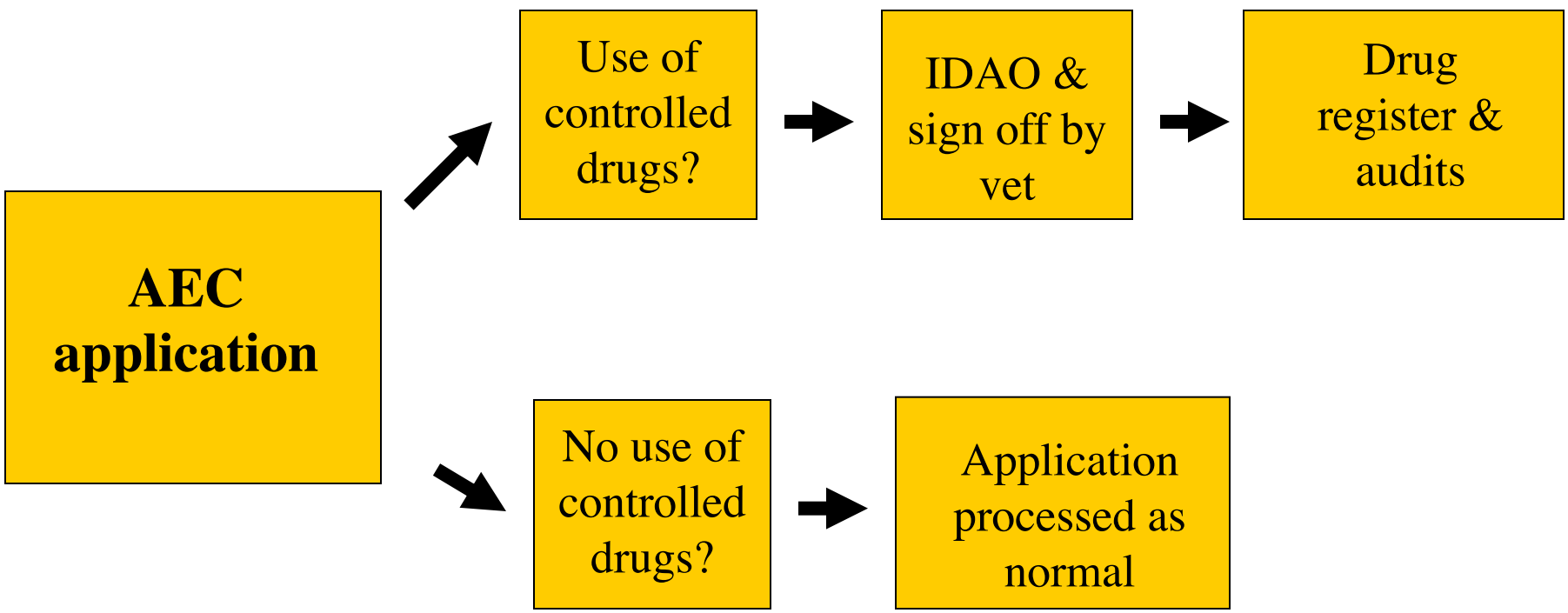
- Skills or qualifications required must be at least the minimum necessary to enable competent use of medicines on animals, as directed by the veterinarian
- All staff/student members authorised to use the IDAO must be named and the skill or qualification levels required by them must be specified

Drug control at the University of Canterbury



Any questions about use of controlled drugs?

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- The procedures required by scientists to use controlled drugs in RTT can be complex and time consuming, especially for the Vet filling out the prescription
- If you are unsure whether the drugs you propose to use are subject to control, please consult the AEC for advice

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Thank you for you attention