Policy for the Use of Experimental Animals

Legal & Regulatory Requirements

1. Teaching and research experiments involving living vertebrate animals may only be performed by staff and students who are licensed under the Animals (Control of Experiments) Ordinance, Cap. 340. A license specifies the type of experiment, type of animal used and places where experiments may be conducted. In addition, special endorsements and permits are required for performing experiments
   (i) for the purpose of attaining manual skill;
   (ii) for the purpose of illustrating lectures; and
   (iii) without administering any anaesthetic or killing the animal.

For teaching experiments, “Bloc License” should be obtained from the Department of Health (DH) by the teaching staff in charge to cover the group of named students involved in individual experiments.

If a licencee would like to conduct an experiment in which specification, including the type of experiment, type of animal to be used and the approved location, differs from those stated on his/her license, an application for a separate licence is necessary.

Every licencee is required to keep an up-to-date record of the particulars of experiments in the form set out as “Form 6” in the Schedule of the Animals (Control of Experiments) Regulations as per http://www.dh.gov.hk/english/useful/useful_forms/files/AL_Form_6_eng.pdf.

Every licencee is also required to submit an annual return to the government by the first day of January each year. This annual return should be in the form set out as “Form 7” in the Schedule of the Animals (Control of Experiments) Regulations as per http://www.dh.gov.hk/english/useful/useful_forms/files/AL_Form_7_eng.pdf.

Application forms for licenses can be downloaded from the website of the DH at http://www.dh.gov.hk/english/useful/useful_forms/useful_forms_ani.html.


3. A valid licence under Cap. 340 does not preclude prosecution under Cap. 169 Prevention of Cruelty to Animals Ordinance: https://www.elegislation.gov.hk/hk/cap169. Investigators must ensure that they adhere closely to the Cap. 340 license conditions, and do not cause unnecessary suffering in the conduct of their experiment, e.g. neglecting to provide adequate pain relief following surgery.

4. Investigators from AAALAC International accredited faculties of the University (e.g. HKUMed) must also adhere to the requirements as set out in the “Guide for the Care and Use of Laboratory Animals (8th Edition) NRC 2011”.

Eligibility and Affiliation

5. Only full-time Teachers (Assistant Professors or above), Lecturers, Research Assistant Professors, Research/Scientific Officers, Research Associates, Post-doctoral Fellows or equivalent ranks are eligible to be “Principal Investigators” (PIs) under section 2 of the application form; staff such as Honorary Professors and Honorary Research Associates may be Co-PI under section 2 if they are accompanied by an eligible PI as mentioned prior; other project members should be listed under section 3 “Other staff/students involved in the experimental procedures.”
6. PIs with affiliations other than their Departments/Schools (i.e. Research Centres/Laboratories) should indicate their Departments/Schools as their affiliations, and the applications should be endorsed by the respective Department Heads/School Directors.

**Application and Protocol Vetting Procedures**

7. Protocols of all experiments involving living vertebrate animals must be scrutinized and approved by the Committee before experiments commence.

8. All new and amended CULATR protocol applications must be submitted via the Computerised Animal Research Ethics System (CARES).

- PIs should take responsibility for completing protocol application forms, however PIs may delegate responsibility to experienced technical grade or postdoctoral personnel for protocol editing prior to final submission. Students or other unexperienced personnel may not be assigned as protocol editors.
- All members of the research team participating in animal experiments must be listed in the protocol.
- All sections of the protocol application form must be completed in full.
- Amendments to approved protocols may be made by the PI on the CARES system.

9. The CULATR will consider amendments to protocols for various reasons to facilitate their research. The type of amendment will determine the mechanism by which amendments are granted or reviewed.

There will be the following mechanism to review amendment requests:

A. Administrative Amendments
   - Changes in the project title
   - Changes in staff/students involved in the project
   - Extension of protocol validity of up to one year

B. Minor Amendments
   - Changes to experimental or animal handling procedures that do not cause serious implication to the welfare of animals
   - Increase in the number of animals of the same species from the original protocol without welfare implications
   - Addition/change of a strain of an already approved species
   - Change in animal sex/age
   - Improvement in analgesic/anaesthetic/antimicrobial regime as advised by a CCMR veterinarian
   - Minor changes that do not have a major impact on animal welfare (e.g. change of drug, route of administration, suture type, surgical approach, site of inoculation, route of blood collection, or food restriction of up to 16 hours)

C. Veterinary Amendments
   - Veterinary Members of CULATR, in consultation with the PI, may make amendments directly in cases whereby improvements in animal welfare are possible. E.g. improvements in anaesthetic/analgesic/antimicrobial regime, or other improvements in animal welfare not already included in the protocol.

D. Major Amendments
   - All other changes to the protocol that are still within the scope and area of investigation of the original proposal, but that are not covered by Administrative or Minor amendments (including increasing animal quota with potential welfare implications).

A new CULATR application of the application is required if changes fall outside the above criteria or as deemed necessary by the Committee.
10. A copy of a valid and up-to-date licence under the Animals (Control of Experiments) Ordinance, Cap. 340 for all personnel involved in experimental procedures must be uploaded to the CARES system. If an application for Cap. 340 licence has been submitted to DH but a licence is yet to be received, a copy of the Cap. 340 licence application form and a copy of the acknowledgement letter from DH may be uploaded to initial the CULATR application. PIs are reminded to upload the valid licences to CARES once they are issued. Individuals performing animal experiments are solely responsible for having valid licences that adequately covers the required procedures, species and locations they are to be engaged with.

11. A minimum of three weeks is expected for the Committee to process the application. Applications may take longer if the information provided is not complete or if there are a large number of applications e.g. before a grant submission deadlines.

Approval for Research and Teaching Protocols

12. Approval of research protocols has a validity period of four years. A one-year extension of the validity period may be requested via an application of amendment. Research projects must not continue beyond the validity period. PIs with approved and current protocols are required to submit an annual review of their protocols to indicate:

(i) whether the projects have commenced or completed,
(ii) whether there have been / will be any changes to the protocol,
(iii) whether there have been any over usage of animals beyond the approved number, and
(iv) whether there have been any unexpected animal suffering / unexpected outcomes that may affect animal well-being (and if so, the subsequent measures used for alleviating animal suffering and protecting animal well-being).

The research protocol will be automatically terminated if such annual review is not provided within 60 days following the approval anniversary of the period.

13. Approved protocols for teaching purpose have a validity of four years, but must be submitted to the Committee for annual review in order to assess whether such experiments are still genuinely necessary to students and to ensure that the number of animals used is well justified and maintained at a minimum. PIs of teaching protocols should notify CULATR of expected teaching schedules so that CULATR members may periodically provide oversight into the use of animals for teaching purposes.

Experimental Procedures

14. PIs should ensure that only the approved types and number of animals will be used and the approved procedures will be carried out. Prior approval from the Committee must be sought in the form of application for amendment if it is necessary to make any changes to an approved protocol.

15. PIs should keep proper record of the sources, types and number of animals used every year. If the animals to be used in a project will be produced by PIs’ experimental breeding colonies (i.e. the required animals will not be bred and supplied by the Specific Pathogen Free Central Breeding Area of the CCMR), PIs should maintain proper breeding colony management and keep correct record of the population size (i.e. “breeder/stock” animals) of these colonies.

16. A copy of the approved protocol should be accessible in the room where the animals are kept and in the research laboratory where procedures will be performed on the animals so that staff can easily make reference to it on site and CULATR members can inspect it whenever necessary.

17. If experiments on live animals are to be carried out as a collaboration with another institution, a Memorandum of Understanding (MOU) for the care and use of laboratory animals at collaborating institution should be established. HKU already has such MOUs with HKUST, CityU, PolyU, CUHK, and the HKBU Dept. Chemistry. HKU owned animals must however not be housed in other institutions overnight without CULATR approval. The PI should also inform the Committee that approval has already been sought from the animal ethics committee of the host institution before commencement of the experiments. No research animals shall be moved between institutions without first seeking endorsement from the research animal facility Director/ Veterinarian of the receiving institution.
18. If the experiments involve the use of hazardous substances and/or other hazards (e.g. infectious agents, radiation, radioactivity, corrosive substances, carcinogens, recombinant DNA, etc.), the Safety Office / University Health Service must be consulted about the safety measures (e.g. containment measures, disposal and decontamination of biohazardous materials, medical surveillance, etc.) before commencement of the experiments.

19. Experiments must be conducted in such a way as to avoid any unnecessary suffering and injury to the animals. The research proposal should not be an unnecessary duplication of previously reported experiments. The experimental design should account for factors that influence experimental validity, e.g. statistical power, blinding, randomization, and should take account of the harms and benefits of the research, making reference to the 3Rs. Any special housing and husbandry requirements for the animals should be clearly stated, including criteria and process for timely intervention, the need for single housing, removal of animals from a study, or euthanasia if painful or stressful outcomes are anticipated.

20. The health and welfare of experimental animals shall be monitored daily. The PI in charge of the experiment shall seek CCMR veterinary assistance as soon as possible or shall allow the animal to be terminated if its continuation may result in unnecessary suffering or injury to the animals.

21. If the experiment or procedure is likely to cause pain and discomfort, the animals shall first be rendered incapable of perceiving pain, by anaesthetisation and/or analgesia, and be maintained in that condition until the experiment or procedure is ended. The only exception to this guideline is where anaesthetisation or analgesia would defeat the purpose of the experiment and data cannot be obtained by any other humane procedure. Such experiments or procedures shall be carefully supervised by the PI (and must be covered by a special endorsement to a Cap. 340 license – see [1] above).

22. Multiple recovery major surgical procedures on the same animal will only be permitted if

(i) the researcher can provide satisfactory scientific justification for doing so,
(ii) the second operation will only be carried out (by PI or delegates with proper training) on an animal after it has fully recovered from the first operation (advice should be sought from CCMR whenever necessary), and
(iii) there will be adequate post-operative care in terms of analgesic and antibiotic coverage for and daily inspection of the animal.

23. Careful monitoring and timely attention to problems during operations increase the likelihood of a successful surgical outcome. Intra-operative monitoring with appropriate documentation should be carried out for animal surgeries. Post-operative care of animals should be provided so as to minimise discomfort and the consequences of any disability resulting from the experiment. Proper surgical (including intra-operative monitoring) record and daily record of post-operative care/treatment should be kept in the room where the animals are held.

24. Pharmaceutical-grade medications should be used whenever they are available. The use of non-pharmaceutical-grade chemicals or substances must be described and justified. Please see relevant policy document on the CULATR website.

25. Social animal species must be socially housed unless prior approval from CULATR has been granted. Please see relevant policy document on the CULATR website.

26. Environmental enrichment should be available to all animals, with additional enrichment made available when single housing is justified or necessary.

27. If it is necessary to euthanise an experimental animal, the animal shall be killed in a humane manner, i.e. in such a way as to ensure immediate death. Justification is required for using physical euthanasia methods like cervical dislocation or decapitation without prior anaesthesia. No animal shall be discarded until after it is dead. Animal carcasses, tissues and associated wastes must be safely disposed of according to the rules laid down by the Safety Office.
28. PIs and their team members should comply fully with the relevant policies, guidelines and references listed under the different sections of the CULATR application form and website.

Training & Competency

29. All personnel involved in conducting animal experimentation should be knowledgeable and competent in the procedures they are to perform. At a minimum, all research personnel involved directly in experimental procedures should undergo training in:

- Euthanasia of Laboratory Animals (AALAS Course 5429);
- Introduction to Health and Safety for those working with animals in HKU (AALAS Course 5764);
- Introduction to Research Animal Use at HKU (AALAS Course 5434).

Note: Research personnel need to login to the HKU Portal to access the AALAS Learning Library.

Personnel not already skilled in surgical procedures or work involving hazards should seek further training in biomethodology, surgical skills or biosafety to ensure competency before experimentation begins.

Veterinary Care

30. The Committee has delegated authority for veterinary care and oversight to the CCMR Veterinary Team under the supervision of the Attending Veterinarian (AV) and the Director of CCMR. CULATR has authorized CCMR veterinarians to have access to all areas involving research animals at the University. Such access must be organized at a regular basis with Schools, Departments, Units, and Centers with the expectation that areas housing animals overnight receive no less than weekly veterinary visits from the CCMR veterinary team. Emergency medical care access to animals must be facilitated by all Schools, Departments, Units, and Centers to ensure prompt treatment or alleviation of pain or distress in research animals. The AV has absolute authority on decisions relating to the welfare of research animals. Whilst consideration for the experimental necessity will be given in consultation with the research team, the decision of the AV on the fate of the research animals that may be sick or suffering shall be final. In addition to veterinary care duties, the CCMR Team will supplement the role of the CULATR in providing Post-Approval Monitoring of protocols and may report to the Committee of any deviations from approved experimental protocols.

Research Ethics

31. PIs and their team members have direct and ultimate personal responsibility for the welfare of animals used in their research/teaching experiments. This responsibility starts from the point of acquisition of the animals to their disposal after completion of the experiments. Please refer to Chapter 4 on “Research Animal Ethics” of the HKU Graduate School publication entitled “Research Integrity: A Guide for Research Postgraduate Students at the University of Hong Kong” at https://www.gradsch.hku.hk/gradsch/publications-newsletters/other-publications.

Enquiries

32. Applicants are advised to review the Frequently Asked Questions on the CULATR website at https://www.med.hku.hk/en/Research/Ethics-and-Integrity/Animal-Ethics (under Useful Information) prior to submitting an enquiry.

33. Enquiries concerning the health of experimental animals may be directed to the CCMR at 3910 2042 or compmed@hku.hk for advice or treatment. Useful references on the care, management and welfare of laboratory animals is available on the CCMR homepage at https://ccmr.hku.hk/.

34. Enquiries about animal ethics applications should be directed to the CULATR Secretariat at culatr@hku.hk.

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