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 licensee 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 license is necessary.

Every licensee 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 licensee is also required to submit an annual return (including information on the kinds and number of animals used, etc.) 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 Department of Health at http://www.dh.gov.hk/english/useful/useful_forms/useful_forms_ani.html.


3. A valid license 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 may be considered as an act of cruelty.

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 (at the grade of Assistant Professors or above), Lecturers, Research Assistant Professors, Research/Scientific Officers, Research Associates, and Post-doctoral Fellows 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 always write their Departments/Schools as their affiliations, and the applications should be endorsed by the respective Department Heads/School Directors or Heads.

Application and Protocol Vetting Procedures

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

8. Application for “amendment” to approved projects is limited to the following categories:

(i) changes in project title;
(ii) changes in staff/students involved in the experimental procedures;
(iii) less than ten percent increase in the number of animals of the approved strain/species;
(Note: For projects involving PI-owned animal colonies, “the number of offspring which will be used in experiments” [i.e. the number quoted in Section 7(a)[ii][III] of the CULATR Application Form] should be used as the basis for calculation of the “increase in percentage of the number of animals required”.)
(iv) minor changes to experimental / animal handling procedures that do not cause serious implications to the welfare of animals; and/or
(v) extension of project duration and approval validity period up to 1 year.

Note: Amendments (i) – (v) are applicable to research protocols, and amendments (i) – (iv) are applicable to teaching protocols.

A new CULATR application or full committee review of the application is required if changes fall outside the above criteria or as deemed necessary by the Committee.

Please submit the following documents for amendments:

(i) Application form for amendment. Please complete the relevant sections (Sections 1 – 3 and 7 and/or 11 and 14 – 16) and return those pages of the application form only;
(ii) A covering letter, signed by the Principal Investigator, listing and explaining the amendments to be made;
(iii) Approval letter of previously approved protocol;
(iv) Protocol application of previously approved protocol (Only Sections 1 – 3 are required for amendments in title. For other amendments, the full protocol is required);
(v) Valid animal licenses of all new staff members.

9. Please attach to the application a copy of valid and updated license under the Animals (Control of Experiments) Ordinance, Cap. 340 for the PIs and other staff/students involved in the experimental procedures. If you have submitted an application for Cap. 340 license to DH but have not received the license from them yet, you may submit a copy of the Cap. 340 license application form and a copy of the acknowledgement letter from DH in order for CULATR to process your protocol application. However, you are required to submit the actual licenses to CULATR when they are issued.

10. Applications have to be typed (i.e. hand written applications will be returned). All sections of the application form must be completed. Please enter ‘Not applicable’ if a section is not relevant, applications with blank fields will be returned as incomplete. The application form can be downloaded from https://www.med.hku.hk/en/Research/Ethics-and-Integrity/Animal-Ethics under Forms.

Note: An electronic CULATR system is progressively being rolled out in 2021 and is expected to replace all paper submissions in due course.

11. Please allow at least two weeks for the Committee to process the application. Progress enquiries may be directed to culatr@hku.hk. Please provide the CULATR reference number or the project title and PI of a new submission, the secretariat endeavors to respond within three working days.
Approval for Research and Teaching Experimental Protocols

12. Approval of research protocols has a validity period of four years. Research protocols have to be re-submitted to the Committee for approval if the projects commence after the validity period. A one-year extension of the validity period may be requested. Research projects must not continue beyond the validity period. The Committee will issue a circular to the principal investigators of approved projects at the end of each year requesting them to submit an annual report indicating:

(i) whether the projects have commenced or have been completed,
(ii) the types and number of animals approved by the Committee/used during a specific reporting period,
(iii) whether there have been/will be any changes in procedures, animal species and numbers, and
(iv) whether there have been any unexpected animal suffering / unexpected outcomes that may affect animal well-being when highly novel variables are introduced such as unanticipated phenotypes in genetically modified animals (if so, the measures used for alleviating animal suffering and protecting animal well-being have to be provided).

The research protocol may be suspended if such annual review is not provided within 60 days of the end of the period.

13. Approved protocols for teaching purpose have to be submitted to the Committee for review every year 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.

14. For experiments which involve the use of animals supplied by “PI-owned animal colonies” (i.e. breeding colonies generated by in-house genetic modification and breeding/stock colonies acquired from overseas/non-Centre for Comparative Medicine Research (CCMR) sources), PIs need to ensure proper animal usage by completing the Monitoring of Animal Usage Forms (downloadable from the link: http://www.med.hku.hk/images/document/04research/culatr/MAUform.pdf). The MAU forms contain information on the animal quota approved by CULATR (Form A) and regular (e.g. weekly) records of actual animal usage (Form B), it should be kept in the room where the animal experiments are carried out for CULATR inspection if necessary. PIs also need to attach a copy of the completed MAU forms when submitting annual reports to CULATR every year. Enquiries on how the MAU forms should be completed may be directed to the CCMR.

Experimental Procedures

15. 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.

16. 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.

17. 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.

18. 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.
19. 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.

20. 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.

21. 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.

22. 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 principal investigator (and must be covered by a special endorsement to a Cap. 340 license – see [1] above).

23. 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 principal investigator or his/her 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.

24. 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.

25. 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.

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

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

28. 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.

29. 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

30. 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 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

31. 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 also 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, and 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 CULATR’s role in providing Post-Approval Monitoring of protocols and may report to CULATR any deviations from approved experimental protocols.

Research Ethics

32. PIs and their team members have direct and ultimate personal responsibility for the welfare of animals which will be used in the 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”. This publication can be downloaded at https://www.gradsch.hku.hk/gradsch/publications-newsletters/other-publications.

Enquiries

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

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

35. Enquiries about animal ethics applications should be directed to the CULATR Secretariat at 3917 9084 / 3917 9147 or culatr@hku.hk.

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