Animal Licenses

1. Teaching and research experiments involving living vertebrate animals may be performed only 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 place(s) 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;
   (iii) without administering any anaesthetic or killing the animal.

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

If a licensee would like to conduct an experiment whose specification, including the type of experiment and type of animal to be used, differs from those stated on his/her license, another 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 (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 on or before 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 (http://www.dh.gov.hk/english/useful/useful_forms/files/AL_Form_7_eng.pdf).

Application forms for licenses are obtainable from the Faculty Office of the Faculty of Medicine and can also be downloaded from the website of the Department of Health at http://www.dh.gov.hk/english/useful/useful_forms/useful_forms_ani.html.

The Laboratory Animal Unit will only issue animals to those licensees who have (a) submitted their annual returns to the Director of Health and (b) provided a copy to the Unit in early January each year.

2. Every licensee under Cap. 340 is advised to comply fully with the Agriculture, Fisheries and Conservation Department’s “Code of Practice for Care and Use of Animals for Experimental Purposes (2004)” which can be downloaded at http://www.afcd.gov.hk/english/quarantine/qua_awc/qua_awc_aw/qua_am_aw_code/qua_am_aw_code.html.

Eligibility and affiliation

3. 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; other staff such as Honorary Professors and Honorary Research Associates should be listed under Section 3 “Other staff/students involved in the experimental procedures”.
4. 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**

5. Protocols for all experiments (including preliminary and pilot experiments) involving living vertebrate animals have to be scrutinized and approved by the Committee beforehand. For an experimental protocol which is “acute” and “non-invasive” in nature and substantially similar in content to previously approved protocol(s), a “fast-track” procedure which takes approximately 10 calendar days for securitization and approval may be used. For protocols on preliminary and pilot experiments, there is also a “fast-track” mechanism in place for vetting.

6. 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 is required if changes fall outside the above criteria or if the Committee deems necessary.

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); and
   (v) Valid animal licenses of all new staff members.

7. Please attach to the application a copy of valid and updated license under the Animals (Control of Experiments) Ordinance, Cap. 340 for the principal investigator(s) and other staff/students involved in the experimental procedures. If you have submitted an application for Cap. 340 license to the Department of Health (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 for vetting/record when they are issued.

8. Applications have to be typed/printed. **All sections** of the application form must be completed. Please enter 'Not applicable' if a section is not relevant rather than leaving it blank. The application form can be downloaded from [http://www.hku.hk/facmed/04research_animal.htm](http://www.hku.hk/facmed/04research_animal.htm). Protocol vetting procedures are also available at [http://www.hku.hk/facmed/04research_animal.htm](http://www.hku.hk/facmed/04research_animal.htm).

9. Please allow at least two weeks for the Committee to process the application.

**Approval for Research and Teaching Experimental Protocols**

10. Approval of research protocols has a validity period of **not more than three years**. Research protocols have to be re-submitted to the Committee for approval if the projects commence after the validity period. Research projects which are still going on after the validity period have to be re-submitted to the Committee for review and approval. 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).

11. Approved protocols for teaching purpose have to be submitted to the Committee for review and approval **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.

12. For experiments which involve the use of animals supplied by “**PI (principal investigator)-owned animal colonies**” (i.e. breeding colonies generated by in-house genetic modification and breeding/stock colonies acquired from overseas/non-LAU local sources), Pls have to ensure proper animal usage by completing the **Monitoring of Animal Usage Forms** (downloadable from the link: [http://www.hku.hk/facmed/images/document/04research/erule/MAU_PI-owned_Forms.doc](http://www.hku.hk/facmed/images/document/04research/erule/MAU_PI-owned_Forms.doc)). 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. Starting January 2010, Pls also have to attach a copy of the completed MAU Forms when submitting the Annual Reports to CULATR every year.

**Experimental Procedures**

13. Principal investigators should ensure that only the approved type(s) and number(s) 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.

14. Principal investigators (Pls) should keep proper record of the source(s), type(s) and number of animals used every year. If the animals to be used in a project will be produced by Pls’ experimental breeding colony(ies) (i.e. the required animals will not be bred and supplied by the Specific Pathogen Free Central Breeding Area of the Laboratory Animal Unit), Pls should maintain proper breeding colony management and keep correct record of the population size (i.e. “breeder/stock” animals) of these colonies.

15. A copy of the approved protocol should be kept 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.

16. If experiments on live animals are to be carried out in another institution, the principal investigator should inform the Committee that approval has already been sought from the animal ethics committee of the host institution before commencement of the experiments.

17. 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 should be consulted about the safety measures (e.g. containment measures, disposal and decontamination of biohazardous materials, medical surveillance, etc.) before commencement of the experiments. Useful guidelines/links are posted on the homepage of the Safety Office at [http://www.hku.hk/safety/](http://www.hku.hk/safety/) and the University Health Service at [http://www.hku.hk/uhs/](http://www.hku.hk/uhs/).

18. Experiments should 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. Any special housing and husbandry requirements for the animals should be clearly stated, including criteria and process for timely intervention, removal of animals from a study, or euthanasia if painful or stressful outcomes are anticipated.

19. The health and welfare of experimental animals should be monitored daily. The principal investigator in charge of the experiment shall allow it to be terminated if its continuation may result in unnecessary suffering or injury to the animals, and shall ensure that the authority to do so is delegated at times when he/she is himself/herself unavailable.

20. 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 be maintained in that condition until the experiment or procedure is ended. The only exception to this guideline is where anaesthetisation 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).

21. 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 registered veterinarians or LAU 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.

22. 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. Please refer to related guidelines and recommended surgical/intra-operative monitoring record forms posted at [http://www.lau.hku.hk/quicklinks/info.htm](http://www.lau.hku.hk/quicklinks/info.htm).

23. Pharmaceutical-grade medications should be used whenever they are available. The use of non-pharmaceutical-grade chemicals or substances should be described and justified.

24. If it is necessary to kill 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.
25. Principal investigators and their team members should comply fully with the relevant guideline(s)/reference(s) listed under the different sections of the CULATR Application Form.

**Research Ethics**

26. Principal Investigators 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 [http://www.hku.hk/gradsch/web/resources/research_integrity.pdf](http://www.hku.hk/gradsch/web/resources/research_integrity.pdf) of the Graduate School website.

**Enquiries**

27. Any enquiries concerning the health of experimental animals may be directed to the Head of the Laboratory Animal Unit (Tel. 2816 8515, E-mail: lauhku@hku.hk), who will give advice and/or treatment as required. A list of useful references/guidelines/links on the care, management and welfare of laboratory animals is available on the homepage of the Laboratory Animal Unit at [http://www.hku.hk/launit/](http://www.hku.hk/launit/).

28. Enquiries about animal ethics applications should be directed to the Committee Secretariat at Tel: 3917 9312 or E-mail: culatr@hku.hk.

November 2014