THE UNIVERSITY OF HONG KONG
COMMITTEE ON THE USE OF LIVE ANIMALS IN TEACHING & RESEARCH

FREQUENTLY ASKED QUESTIONS

Contents

A. Protocol Applications

1. What are the documents required?
When submitting a new protocol application, please ensure that:

i. The **updated version** of the application form is completed. The most updated form can be downloaded from http://www.med.hku.hk/v1/research/research-ethics/animal-ethics-culatr/;

ii. Section 14 of the application form is signed by the Principal Investigator(s)/staff in charge of the research project/teaching practical listed in Section 2 and all staff/students listed in Section 3(a)*. If the Principal Investigator (PI) is the Head of Department/Centre, endorsement is still required and the PI has to sign Section 15 of the form; and

iii. **Valid and relevant** licenses under the Animals (Control of Experiments) Ordinance, Cap. 340 of all staff involved are included.

(Note: 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.); and

iv. If your protocol application is similar to a previously approved application submitted to CULATR, a copy of the **approval letter** should be submitted.

* Except for students being taught in teaching practicals.

2. How long does it normally take for a protocol to be approved?
On average, a protocol requires around 1 month to be approved, which includes the time taken for CULATR members to consider the application *and* Principal Investigators (PIs) to respond to the comments of CULATR members. However, processing time may vary depending on the number of applications received within a period of time and PIs are recommended to submit their applications in a timely manner to prevent delay, e.g. for

grant submissions. Documents with details on the protocol vetting process and the time taken can be found on the CULATR website.

3. Can I submit my protocol application by fax/email/etc.?
Yes, the CULATR Secretariat also accepts applications by fax and email. Applications may be faxed to 2818 4913 (it is recommended to state the total number of pages on a fax cover sheet), or emailed to culatr@hkucc.hku.hk (signatures and supporting documents are required for applications emailed to CULATR).

4. My project involves several animal experiments. Do I need to submit multiple applications?
No. You may submit one application for the project if the experiments are inter-related and under the same theme, but you are required to list and provide details of **all** animal experiments involved.

5. Who are eligible to be a Principal Investigator (PI) under Section 2 of the application form?
Only full-time Teachers (at the grade of Assistant Professors or above), Research Assistant Professors, Research/Scientific Officers, Research Associates and Post-doctoral Fellows are eligible to be PIs; other staff such as Honorary Professors and Honorary Research Associates should be listed under Section 3 "Other staff/students involved in the experimental procedures.

6. If I am affiliated to a research Centre/Laboratory other than my Department/School, what should I write for my affiliation in Section 2 and 3 of the application form?
You should write your Department/School as your affiliation and your application should be endorsed by your Department Head/School Director.

7. My project involves different species/strains of animals. Do I need to submit multiple applications?
You may submit one application for the project, but you are required to list clearly the animal species/strains that you will use and provide justification.

8. I would like to submit an application for a Teaching Experiment protocol. What should I pay attention to?
For Teaching Experiment protocols, the application process and documents required are similar to Research Experiment protocols. However, you are required to submit both the **Cap. 340 License (Cap. 340 Form 2) and Teaching Permit (Cap. 340 Form 4)** of the Teacher-in-charge. A **Bloc License** is required for **all** students involved in the Teaching Experiment (please refer to Section B of this FAQ for details). In addition, a search should be done by the Teacher-in-charge on the websites listed under Section 6 regarding non-animal models which can be used as acceptable "alternatives to experiments on live animals".

9. I would like to breed/maintain my experimental animal line(s) without performing procedures on them. Do I have to obtain CULATR approval?
Certain investigators may find it necessary to breed and maintain their line(s) of experimental animals for future use. A separate protocol application must be made for breeding and maintenance of animal lines. Normal application procedures (e.g. application vetting, relevant documents and licenses) will apply.

10. What is the "fast-track" processing procedure? Can my application be processed via fast-track?
Protocol applications which are **"acute" and "non-invasive" in nature, and similar to an application previously approved by CULATR** could be considered via the "fast-track" processing procedure. Applications considered via "fast-track" take around 10 calendar days to be considered by Committee members. There is also a "fast-track" processing procedure for pilot or preliminary experiments.

11. What are pilot/preliminary experiments?
These are small-scale experiments that involve minimal number of animals. Occasionally, investigators may have protocols which include procedures which have not been encountered or performed before and the outcome of the procedures is uncertain. Pilot/preliminary experiments are therefore used to assess the outcomes and effects on the well-being of experimental animals.

12. I would like to make an amendment to my approved protocol. What should I pay attention to?
Amendments to previously approved applications should meet certain criteria. Please refer to Section 6 of the "Guidelines for the Use of Experimental Animals" (http://www.med.hku.hk/images/document/04research/culatr/culatr.pdf) or the CULATR Protocol Vetting Procedures (http://www.hku.hk/facmed/images/document/04research/culatr/protocol-flowchart.pdf) for details and documents required. Please submit **a cover letter that lists, and explains if necessary, the amendments to be made**. To save paper and support the environment, please submit the **relevant pages** of the application form **only**.

13. I am a researcher of the University of Hong Kong, but the animal experimentations of my project will not be conducted at the University of Hong Kong. Am I still required to submit my protocol to CULATR for approval?
No. If animal experiments are not conducted at the University of Hong Kong, approval from the CULATR is not required. However, you should inform the CULATR that approval has already been sought from the animal ethics committee of the host institution / organization before commencement of the experiment.

14. Do I need CULATR approval for experiments which only involve tissue collection after euthanasia of the animals?
If you or staff under your project would be euthanizing live animals to obtain the required tissue(s) for your experiments, then animal ethics approval from CULATR **would be required**. However, if you would be obtaining tissue(s) from already euthanized animals (e.g. euthanized by other investigators for another project, or from one of your previous projects which already has CULATR approval), then animal ethics approval **would NOT be required**. For details on the necessity to obtain Cap. 340 licenses from the Department of Health, HKSAR, please see **Question 4 of Section B** of this document.

B. Animal Licenses

1. Are Cap. 340 licenses required for all staff members / students involved in the experiment?
All staff members / students who are involved in the experiment and **performing experimental procedures on the animals** are required to have Cap. 340 licenses **relevant to the animal species and experimental procedures**. Please see the Department of Health website for details on applying for a relevant Cap. 340 license.

(http://www.dh.gov.hk/english/useful/useful_forms/useful_forms_ani.html).

2. Do I need to keep an updated log-book to fulfill the responsibility Cap. 340 licensees?

The Animal (Control of Experiments) Regulations stipulate that every licensee shall keep up-to-date records of all licensed experiments performed by him/her in the form set out as "Form 6" and shall render to the Director of Health on or before the 1st day of January of each year a return in the form set out as "Form 7" of all licensed experiments performed by him/her during the preceding twelve months. Therefore, every Cap. 340 licensee has to keep a properly completed log-book to record all his/her completed experiments. Please note that Department of Health officials and CULATR may carry out arranged and/or unannounced inspection visits in order to check compliance of licensees with the licensing conditions. Licensees may also be requested by the Department of Health to submit their "Form 6" for inspection.

3. I have submitted an application for the Cap. 340 license to the Department of Health, but have not received the license from them yet. Can I submit my protocol application to CULATR while I am waiting for my license to be issued?

Yes. You may submit a copy of the application form(s) for Cap. 340 license (Cap.340 Form 1) together with a copy of the acknowledgement letter from the Department of Health 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**.

4. What are the licenses required for a Teaching experiment protocol?

The Teacher-in-charge and supporting staff (e.g. technicians) are required to submit both the **Cap. 340 License (Cap. 340 Form 2) and Teaching Permit (Cap. 340 Form 4)** when submitting the protocol application to CULATR. A **Bloc License** that covers **all the students** attending the teaching practical must be obtained from the Department of Health prior to the commencement of the teaching experiment. Details on the application procedures for a Bloc License can be found in the FAQ of the Department of Health website (http://www.dh.gov.hk/english/useful/useful_forms/files/AL-FAQ_eng.pdf)

5. Do I need to obtain Cap. 340 licence if the experiment only involves collection of tissues/organs?

According to the advice given in the FAQ of the Department of Health (DH) website (http://www.dh.gov.hk/english/useful/useful_forms/files/AL-FAQ_eng.pdf), it is not necessary to apply for a Cap. 340 licence *if an animal is killed before any procedure is performed on it.* However, please play safe by consulting DH (Tel: 2961 8645 / E-mail: ro_al@dh.gov.hk) and attach a copy of their written reply to your application if you have to perform euthanasia procedures on an animal before collecting tissues/organs from the carcass.

C. Application Form Section 6 - Harm-Benefit Analysis

1. What points should I consider for "Harm-Benefit Analysis"? Can you give an example?

(i) Points to consider when answering questions on "Harm-Benefit Analysis":

Harm	Benefit
1. Will your experimental procedures cause: (a) Physiological disturbance to animal: e.g. nausea, fever, skin irritation, pain. (b) Psychological disturbance to animals: e.g. distress, behavioural disorder, fear, anxiety, boredom. 2. If so, what will be the duration that the animal will experience these disturbances? 3. If so, will these disturbances be alleviated? 4. Is there replication/duplication of previous work in your protocol? 5. Is your experimental design based on well established procedures or protocols?	A. What is the aim of your research? B. What is the relevance of this project to other studies in this field of research and what might be the implications for other areas of research? C. Will your project benefit human/animal kind or advance humanity? If so, how? How achievable or likely are these benefits to occur? D. Are there any practical applications that could result from your project? E. If this is on-going work, how does the present proposal relate to what has gone before? What progress was made in previous studies, and what scientific and/or other benefits have resulted?

(ii) An example of "Harm-Benefit Analysis" for a project which involves invasive surgery and post-operative behavioural tests:

Harm	Benefit
1(a). Physiological disturbance will be caused to animals in the form of a single invasive surgical procedure. 1(b). Psychological disturbance will be caused to animals in the form of behavioural testing. 2&3. The animals will undergo one surgical procedure, the related pain will be appropriately alleviated with analgesics. Behavioural tests will be performed weekly for one month and are widely recognized, references are attached. 4. Our research is building upon early experimental results (references attached). There may be some duplication of previous work as we validate the animal model, but this project also will cover novel research. 5. The surgical procedure is based on the attached reference. It may need to be refined for research into "Molecule A", so we are requesting 10 extra mice for a pilot study.	A. To advance the understanding of 'Molecule A' in a surgical setting, and in the post-operative behavioural setting. B. 'Molecule A' has been newly discovered (see attached reference) and a deeper understanding of this molecule may also benefit other fields such as physiology, biochemistry, medicine, surgery and neuroscience. C. Understanding more about 'Molecule A' may result in discovering a new target for pharmaceuticals to be developed. This study will be able to determine how likely or unlikely any benefits can be developed. D. Yes, this study could lead to the ultimate development of new pharmaceuticals. E. This is a newly discovered molecule, and little research has been performed previously (see attached reference) therefore we hope to expand on what is currently known.

D. Application Form Section 7 - Animal Requirements

Please complete Section 7(a) and 7(b) as detailed as possible, including a clear breakdown (e.g. by using a table) and explanation of the number of animals required.

1. Can I use multiple species/strains of animals?
Yes. Please list clearly the animal species/strains and the required quantities that you will use in Section 7(a) and provide justification in Section 7(b).

2. Can I obtain the animals required in my experiment from another researcher in HKU who maintains a "PI (Principal Investigator)-owned Breeding Colony" under a separate CULATR-approved project?
Yes. You need to complete Section 7(a)[ii] for the animals to be obtained from another researcher (i.e. you need to enter the breeding colony data, estimated cage requirement, CULATR Ref. No. of the other researcher's project which involves a "PI-owned Breeding Colony" that you will obtain animals from and other related details in this section).

3. What is the meaning of "Breeder" and "Stock" in Section 7(a)[ii]?
"Breeder" refers to the estimated number of male and female breeders in the breeding colony at any one time. "Stock" refers to the estimated quantity of weaned offspring in the breeding colony at any one time (note: these weaned animals include replacement breeders, offspring which will be used in the experiments and surplus animals which are unsuitable for use in the experiments). Therefore, please do not enter the estimated cumulative/total number of "Breeder" and "Stock" animals for the whole project in this section.

E. Application Form Section 11 - Experimental Procedures

1. Can I include multiple experiments in my project?
Yes, as long as the experiments are inter-related and under the same theme. Please list **all** animal experiments involved and provide details of the procedures for **each experiment** in Section 11(a)[ii].

2. How can I obtain information on commonly used drugs for laboratory animals (e.g. drugs used for analgesia, anaesthesia and euthanasia)?
Information on dosages and route/frequency of administration for commonly used drugs is available at http://www.hku.hk/local/launit/content/info/drug_tables.pdf and http://www.hku.hk/facmed/images/document/04research/culatr/LAU_VC-Guidelines.pdf. Please use **generic names** of drugs to be used and not commercial brand names to avoid confusion. Dosage, route, frequency, duration, site and volume of drug administration should be stated clearly in Sections 11(c) and/or 11(j) as appropriate.

3. Is it necessary to keep surgical (including intra-operative monitoring) and post-operative care records for animals used in my experiments?
As mentioned in Section 22 of the "Guidelines for the Use of Experimental Animals" (available at http://www.med.hku.hk/images/document/04research/culatr/culatr.pdf), 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.

4. Can I rely on the staff at the Laboratory Animal Unit to fully look after the animals used in my experiments?
Researchers who use animals for scientific purposes have direct/ultimate personal responsibility for all matters relating to the welfare of the animals they use. Therefore, in addition to the Laboratory Animal Unit (LAU) staff, the investigator(s) and his/her team member(s) are also responsible for monitoring the animal well-being, keeping proper surgical (including intra-operative monitoring) record, carrying out post-procedural/operative observation/care and performing inspection/treatment of sick animals on a daily basis. Please refer to related guidelines and recommended surgical/intra-operative monitoring record forms posted at http://www.lau.hku.hk/quicklinks/info.htm.

5. Can I use "cervical dislocation" to euthanise mice in my experiments?
Cervical dislocation should be performed on anaesthetized animals only and must be carried out by properly trained personnel. Cervical dislocation of non-anaesthetised animals is not recommended unless there are scientific justifications to do so. Otherwise, the recommended euthanasia method for mice is by using an overdose of pentobarbitone (100-150 mg/kg, i/p).

6. Should I use halothane or isoflurane to euthanize animals?
Isoflurane is preferred to halothane because it induces anaesthesia more rapidly and is less hepato-toxic. Effective procedures/gas scavenging apparatus should be in place to reduce animal worker exposure to anaesthetic vapours.

7. How can I obtain advice from the Safety Office for Section 11(k)?
Please refer to the University's Safety Office website for useful information and contact details: http://www.hku.hk/safety/.

F. Monitoring of Animal Usage and Annual Report Forms

1. What are the "Monitoring of Animal Usage of PI-Owned Colonies (MAU) Forms"?
These forms (Forms A and B) are designed to further improve the monitoring by the LAU and CULATR of animal usage in research projects which involve the use of "**PI-owned animal colonies" (i.e. breeding colonies generated by in-house genetic modification or breeding/stock colonies obtained from overseas/local non-LAU sources)**, due to the increasing number of research projects involving the use of "non-LAU animals" (i.e. animals which are not supplied by the SPF Central Breeding Area of the LAU). PIs with self-owned colonies will be required to fill in the new "Monitoring of Animal Usage of PI-Owned Colonies Forms" starting from January 1, 2009.

2. What is the difference between the MAU Forms A and B?
Form A – CULATR-approved Animal Quota
This form summarizes the data in Section 7(a) of the CULATR application form. One Form A is required for each CULATR-approved protocol.

Form B – Annual Report on Animal Colony Data and Actual Animal Usage
This form records the animal colony data and usage on a regular (e.g. weekly) basis. One Form B can be used for each or more than one animal strain/line depending on the complexity of the breeding system required by individual protocols. For PIs who have

requested the LAU to provide husbandry / breeding services for their colonies, LAU staff would be responsible for filling in the MAU Forms on the PIs' behalves.

3. Do I have to complete the MAU Forms if I only use animals supplied by the SPF Central Breeding Area of the LAU?
No.

4. How will the forms be used by the LAU and CULATR?
The LAU will carry out random checking of the completed forms which should be kept in the animal rooms and available for inspection by CULATR members whenever necessary. PIs concerned are also required to attach a copy of these forms with the Annual Report starting from the 2009 reporting exercise (i.e. for the Report to be submitted in January 2010 covering the reporting period of January 1, 2009 to December 31, 2009).

5. Who should I contact if I have other questions on filling in the MAU forms?
The Laboratory Animal Unit (LAU) welcomes users to contact them for any queries on completing the MAU form. Please contact the LAU at Tel: 2816 8515 / Email: lauhku@hku.hk.

G. Annual Reports

1. What are the numbers that I should complete for Part D?
Part D should be completed with the following information:

(i) Total number and strains of animals approved by CULATR for the entire project (e.g. 3 years), and not just for the report period:- If the animals were/will be obtained from the LAU, please complete column 1 & 2 of the table in Part (a). However, if the animals are/will be bred or purchased from other sources by the PI, please complete Part (b) and/or (c) and attach the MAU forms as appropriate. For information on completing the MAU forms, please refer to Section E above.

(ii) Total number and strains number of animals used in the experiment(s):- If the animals were obtained from the LAU, please complete column 3 & 4 of the table in Part (a). However, if the animals were bred or purchased from other sources by the PI, please attach the completed MAU forms as appropriate. For information on completing the MAU forms, please refer to Section E above.

2. What is meant by "Unexpected Outcomes" in Part F?
Fundamental to scientific inquiry is the investigation of novel experimental variables. There is a potential for "unexpected outcomes" that may affect animal well-being when highly novel variables are introduced (e.g. unanticipated phenotypes in genetically modified animals), therefore more frequent monitoring of animals is required to ensure that their well-being is not adversely affected and timely measures are taken to alleviate unexpected animal suffering.

H. Frequent Mistakes made by Applicants:

i. **Out-dated application form** – Applicants should download the application form from the CULATR website (http://www.med.hku.hk/images/document/04research/culatr/culatr-appform.doc) in order to ensure that the most up-to-date form is used. Applicants using outdated forms will be asked to resubmit the application using the updated form.

ii. **Incomplete sections** – Applicants are reminded to complete **ALL** sections of the application form properly. Please put "N/A" or "Not applicable" in sections that are not relevant to your protocol application. Incomplete forms cannot be processed and will be returned to applicants.

iii. **Inadequate description of experimental procedures –** If the project involves "multiple surgical procedures", please provide justifications in Section 11(a)[ii] and list clearly the number of surgical procedures involved, procedural details (including pre-operative skin preparation and suture materials to be used) as well as the interval between each surgery. If dosing and tissue (e.g. blood) collection are required, full details on methods of restraint, route of administration, collection site, volume, frequency of dosing/collection, *etc*. have to be given.

iv. **Missing or irrelevant Cap. 340 licenses** – Please ensure that all investigators and staff involved in the experiments hold **valid and relevant** Cap. 340 licenses. Applicants are reminded to check that their licenses cover the relevant **experimental procedures and animal species** and consult the Department of Health whenever necessary.

v. **Using Commercial drug names** – Please fill in generic names of drugs to be used and not commercial names to avoid confusion.

vi. **Missing information on safety measures** – If the experiments involve the use of hazardous substances and/or other hazards (e.g. infectious agents, corrosive substances, carcinogens, etc.), the Safety Office / University Health Service should be consulted on the safety measures required.

vii. **Incomplete signatures** – Declaration Signatures of **ALL** parties involved in the animal experiment (i.e. the Principal Investigator(s)/staff in charge of the research project/teaching practical listed in Section 2 and all staff/students listed in Section 3[a]*) and Endorsement Signature(s) of Head(s) of Department(s)/Centre(s) must be included in Section 14 and Section 15 respectively of the application form. A Principal Investigator who is the Head of Department/Centre should also sign Section 15 as an endorsement of the application.

* Except for students being taught in teaching practicals.

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