Notes to Applicants -
Animals (Control of Experiments)
Ordinance, (Cap. 340)

Health Technology and Advisory Division
Department of Health
HKSAR Government
Background (1)

- The Animals (Control of Experiments) Ordinance (Cap. 340) provides for the control of experiments on living vertebrate animals

- In Cap. 340-
  - “Academic institution” includes universities, university colleges, hospitals, medical schools, agricultural colleges, farm schools, and any other similar institutions
  - “Animal” means a living vertebrate animal
  - “Experiment” means any experiment performed on an animal and calculated to give pain
  - “Licensee” means a person licensed under section 7 of the Ordinance
  - “Licensing Authority” means the Director of Health
According to Cap. 340,

- No person except a licensee shall perform any experiment
  - i.e. Any person who is involved in performing an experiment on animal should apply for a licence/permit/endorsement(s) for that specific experiment

- The Licensing Authority may grant a licence to any person to perform any experiment for any purpose specified in such licence during such period at such place, and subject to such conditions, in addition to the conditions specified in the Ordinance, as he may think fit
Type of licence/ permit/ endorsement(s)

1. Licence to Conduct Experiments
   - Applicable to all animal experiments

2. Endorsement to Authorize Experiments to Attain Manual Skill
   - Example: To practise open heart surgical techniques using pigs

3. Teaching Permit
   - To perform an animal experiment for the purpose of illustrating a lecture
   - Example: To demonstrate the physiology of respiratory system using mice

4. Endorsement to Authorize Experiments without Anaesthetics or without Destroying the Animal
   - For experiment that would necessarily be frustrated by the performance of such experiment under any anaesthetic; or by killing the animal on which such experiment is performed before it recovers from the influence of any anesthetic
   - Example: To study the efficacy of a newly discovered analgesic agent using mice
Validity period

- Licence to Conduct Experiment with/ without endorsement(s): 2 years

- Licence to Conduct Experiment with Teaching Permit: 1 year
Application procedures

Applicant submits completed application form and the annex by email, fax or post

Are the application form and annex complete?

No

Department of Health (DH) sends an acknowledgement of receipt to the applicant by fax

DH processes the application and may request for further information by email

Is the information sufficient?

No

DH informs the applicant the result of the application by fax and post

Yes
Application procedures: Renewal of licence

- **Renewal of licence**
  - to continue with the same animal experiment as specified in the existing/previous licence
  - i.e. the **same experimental procedures** under the type of experiment(s) and the **same purpose of experiment(s)**

- **Procedure of renewal application**
  - Submit completed application form and the annex **3 months** before the expiry date of the existing licence, preferably together with a copy of the licence to be renewed and completed annual return (Form 7)
  - In the annex -
    - Quote the reference number of the licence he/she wishes to renew and indicate whether the licence has expired or not
    - Declare in the Annex that he/she will comply/have complied with the requirements in the Ordinance and the Regulations as appropriate
(1) **Type of licence/ permit/ endorsement(s)**

a) a Licence under section 7 of the Animals (Control of Experiments) Ordinance (Cap. 340)

   **Form 2: Licence to Conduct Experiments**

b) an endorsement / thereto / *to my existing Licence No.__ dated__ / under section 8 of the said Ordinance

   **Form 3: Endorsement to Authorize Experiments to Attain Manual Skill**

c) a teaching permit under section 9 of the said Ordinance

   **Form 4: Teaching Permit**

d) an endorsement to / the said Licence / *my existing Licence No.__ dated__ under section 10 of the said Ordinance.

   **Form 5: Endorsement to Enable Performance of Experiments Without Anaesthetics or without Destroying the Animal**
Information required in the Application Form

(2) Grounds for application

- An explanation of how the proposed experiment advances scientific knowledge and provides benefits to human beings, animals and/or plants, or tests any former discovery alleged to have been made for the advancement of such types of knowledge OR;
- By the order of any judge or district judge
- Reason(s) why living vertebrate animals have to be used for the experiment
- Justification for application for an Endorsement to Authorize Experiments to Attain Manual Skill and/or a Teaching Permit if applicable

(Notes: Justification for application for an Endorsement to Enable Performance of Experiments Without Anaesthetics or Without Destroying the Animal shall be provided in the Annex to application form.)
(3) Type of experiment(s)

- Type(s) of animals
- A brief description of the procedures of the experiment(s)
- Experimental procedures/conditions which may cause pain and distress to the animals
- Measures to be taken to minimise such pain and distress in the animals
- How conditions/well-being of the animals will be monitored during the experiment
- How the animals will be treated at the end of the experiment, e.g. sacrificing the animals
- Adequate description of the experiment(s) in order to demonstrate how the purpose(s) of the experiment(s) can be achieved by performing the experiment(s)
(4) Purpose of experiment(s)

- Research question(s) for the proposed experiment(s)-
  - For the purpose of the advancement by new discovery of physiological knowledge, or of any knowledge which will be useful for saving or prolonging life, or alleviating suffering, or for combating disease whether of human beings, animals or plants
  - For the purpose of testing any former discovery
  - By the order of any judge or district judge

- Type(s) of manual skill to be attained; and/or
- Purpose(s) of the lectures and the type(s) of knowledge and skill the attendants of the lectures could acquire from the proposed experiment
(5) Place where experiment(s) may be conducted

- the full address(es) [including the room number, floor number, name of building and institution] of the place(s) where the proposed experiment will be conducted
Information required in the Annex to application form

- To indicate application for new or renewal of licence
- To make declaration on their compliance with the legal requirements to keep records of experiments (Form 6) and render returns of experiments (Form 7) to the Director of Health and to hold a valid licence before conducting an experiment
- To indicate the wish to communicate via SMS on matters related to application/ licence
- To provide personal particulars for communication and law enforcement
- To obtain a department chop from an authorized person of the institute/ company, as an endorsement of the application by the institution
A. To keep records

- Every licensee shall keep **up-to-date records** in the form set out as **Form 6 (Record of Experiments)** in which he shall record the particulars of all experiments performed by him.

- Any person who contravenes the above provision shall be guilty of an offence and shall be liable on summary conviction to a fine of HK$500* and to imprisonment for 3 months.

*Note: Under section 113C (2) of the Criminal Procedure Ordinance, Cap. 221, where an Ordinance, provides for a fine, other than an excluded fine, for an offence expressed as an amount of money, the fine shall be deemed to be a fine at the level relevant to the amount of the fine in a prescribed table. For a $500 fine, the level applied should be Level 1 and thus, the fine could be up to $2000*
Legal responsibilities of licensee -
To permit inspections

B. To permit inspections

- To inspect any records kept by licensee
- For the purpose of securing compliance with the provisions of Cap. 340, any place specified in such licensee’s licence for the performance of experiments
- Licensing Authority will conduct announced and/or unannounced inspection visits
- Licensees may also be requested to submit their Form 6 to the Licensing Authority
Legal responsibilities of licensees

To render Form 7 (Return of Experiments)

C. Duty to render returns

- Every licensee 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 (Return of Experiments) of all experiments performed by him/her during the preceding twelve months.

- Any person who contravenes the above provision shall be guilty of an offence and shall be liable on summary conviction to a fine of HK$500* and to imprisonment for 3 months.

- Licensing Authority will send reminder letters to:
  - Licensees via email and SMS (if consented)
  - Heads of Department to seek their assistance in reminding the licensees from their Department in Nov/Dec

*Note: Under section 113C (2) of the Criminal Procedure Ordinance, Cap. 221, where an Ordinance, provides for a fine, other than an excluded fine, for an offence expressed as an amount of money, the fine shall be deemed to be a fine at the level relevant to the amount of the fine in a prescribed table. For a $500 fine, the level applied should be Level 1 and thus, the fine could be up to $2000.
Annex to Form 7 (Return of Experiments)

- To provide personal particulars for communication and law enforcement
- To indicate if the licensee has completed or stopped the experiment, or he/she is going to leave his/her academic institution/organization before the end of the specified period granted in the licence
Tips on application-
Application on behalf of a group of students/participants

- For academic purpose or attaining manual skill under the supervision of teaching staff
- Teaching staff: granted a licence to conduct the experiment and a teaching permit for that particular experiment

Application procedures:
- Submit an application with a list of names, qualifications and unique identifier (e.g. student number) of those students or participants
- Provide the name(s) of the teaching staff involved and the reference number of the licence and teaching permit that has already been granted for that particular experiment
Tips on application- Laboratory staff performing the same procedures in different experiments

Application procedures:

- Submit an application and a list of licensees/ departments that the applicant is going to assist

- In the application form:
  - Section “Type of experiment”: provide a summary of experimental procedures that he/ she will perform and the measures that will be taken to prevent the animal(s) from experiencing pain during the procedures
  - Section “Purpose of experiments”: indicate that the aim of the proposed experiments and procedures is to assist licensees in their experiments as stated in their respective licences
Tips on application- Application for a licence of the same experiment of my colleagues’ licences

- If any of the investigators has already submitted the application form/ obtained a licence,

  - state the reference number given by the Licensing Authority in a covering letter/ email and attach a copy of the licence issued to the application form for reference, if applicable
Frequently asked questions - Variation of licence

- Variation of place(s) of conducting experiment or change of department within the same institution is allowed
  - Inform us in writing of the full address(es) of the proposed place(s) for experiment or the name of the new department
  - Revised licence superseding the existing one will be issued if approved

- Other proposed changes e.g. change of institution, the type(s) of animals, experimental procedure(s) and method(s) used to sacrifice the animals
  - Require submission of a new application
Frequently asked questions - Leaving your institution/ company

- If you will no longer perform experiments in the specified place on the licence
  → you may terminate your licence

- Inform the Licensing Authority in writing of the effective date on which you leave the academic institution/ company

- Submit a Form 7 (Return of Experiments) and the Annex for experiments performed during the preceding 12 months of the leaving date, except those which have been covered by the previous return
Frequently asked questions-
Experiment on sacrificed animals

- Cap. 340 provides for the control of experiments on living vertebrate animals, a licence is NOT applicable to the experiments which will only involve animals after they are sacrificed (including dead animal body dissection or tissue collection from a dead body).

- When handling the animals, please comply with the Prevention of Cruelty to Animals Ordinance (Cap. 169) which can be found at <https://www.elegislation.gov.hk/hk/cap169>.