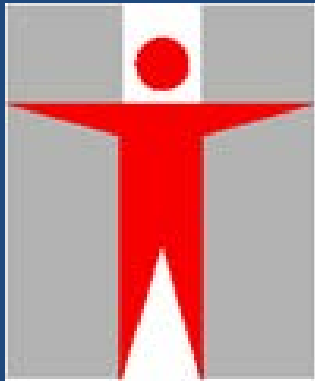


Application for licence under the Animals (Control of Experiments) Ordinance, (Cap. 340)



October 2013

Special Health Services
Department of Health
HKSAR Government

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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

Background (2)

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

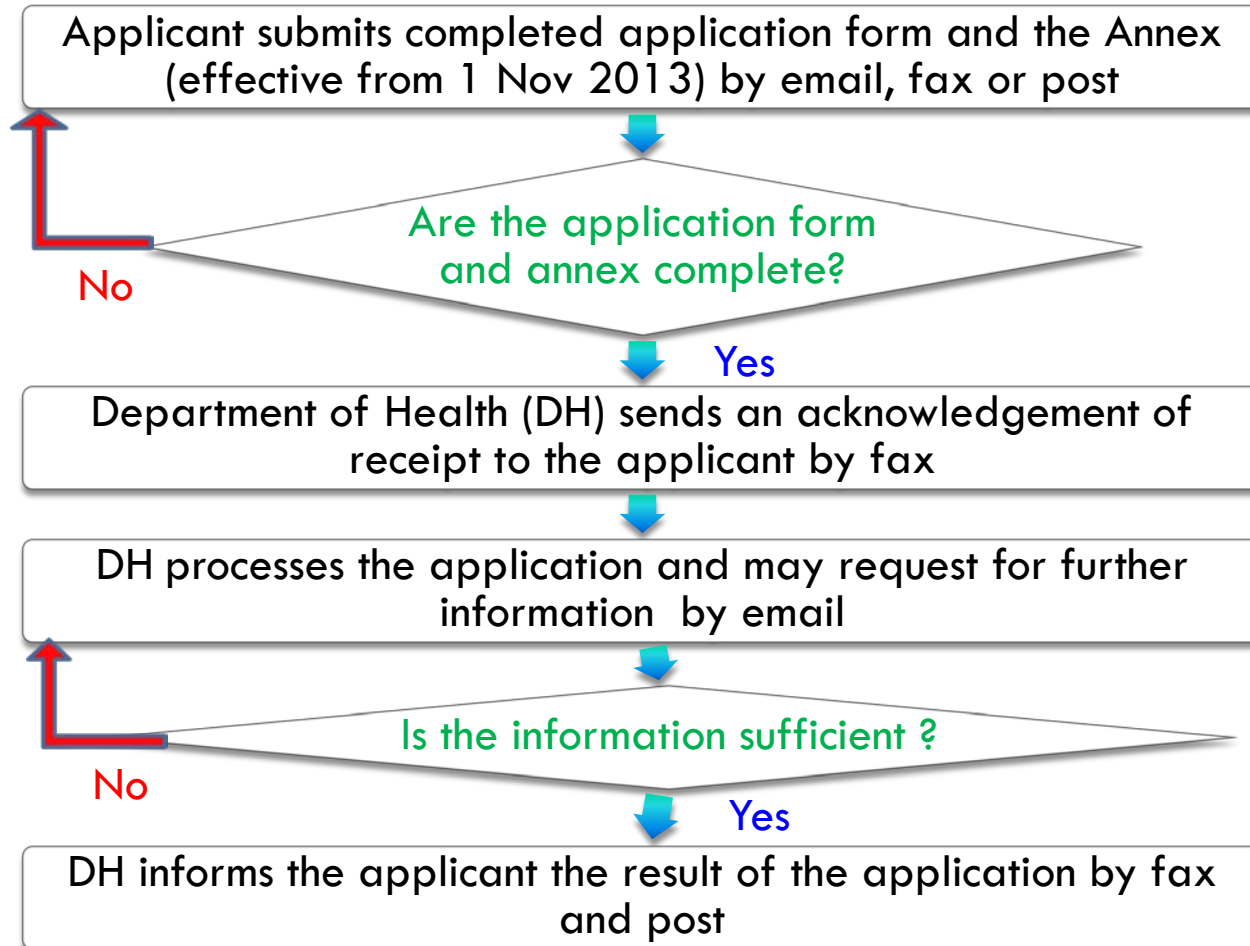
Type of licence/ permit/ endorsement(s)

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



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

Information required in the Application Form

□ Sample Application form

ANIMALS (CONTROL OF EXPERIMENTS) REGULATIONS

FORM 1 Application Form

To : The Director of Health

I, _____
of _____

on the grounds hereinafter mentioned, hereby apply for —

- * { (a) a Licence under section 7 of the Animals (Control of Experiments) Ordinance (Cap. 340).
(b) an endorsement / thereto / *to my existing Licence No. _____
dated _____ / under section 8 of the said Ordinance.
(c) a teaching permit under section 9 of the said Ordinance.
(d) an endorsement to / the said Licence / *my existing Licence No. _____
dated _____ / under section 10 of the said Ordinance.

Grounds for application.

Type of experiment(s).

Purpose of experiment(s).

Place where experiment(s) may be conducted.

Qualifications of Applicant and any posts held.

Dated _____

Signed _____

*Delete as appropriate.

Information required in the Application Form

□ 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

□ 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.)

Information required in the Application Form

- **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)

Information required in the Application Form

- **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

Information required in the Application Form

- **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 Annex

- Sample Annex
(effective from
1 Nov 2013)

Annex

The section below is not part of Form 1 but information supplied would help avoid unnecessary delay in processing your application.

Please put a 'tick' to the box against each of the followings which are applicable to your application.

- I have not been granted a licence for the experiment under application before [please go to (2) and (3a or 3b) only] **OR**
 - I am the holder of a valid licence for the experiment under application (Reference number of licence: _____) [please go to (2) and (4) only] **OR**
 - I am not the holder of a valid licence for the experiment under application but I have been previously granted a licence for the experiment under application which has now expired (Reference number of latest licence: _____) [please go to (2) and (5) only]
- I hereby declare that in accordance with Regulations 4 and 5 of the Animals (Control of Experiments) Regulations, Cap. 340A ("the Regulations"), I shall keep up-to-date a book in the form set out as Form 6 in the Schedule to the Regulations and I shall render to the Director of Health on or before the 1st day of January each year a return in the form set out as Form 7 in the Schedule to the Regulations of all experiments* performed by me during the preceding twelve months
- (a) Application for a licence without an "Endorsement to Enable Performance of Experiments Without Anaesthetics" under section 10 of the said Ordinance -
 - I confirm that throughout the whole of the experiment the animal is under the influence of some anaesthetic of sufficient power to prevent the animal feeling pain; and if the pain is likely to continue after the effect of the anaesthetic has ceased, or if any serious injury has been inflicted on the animal, the animal is killed before it recovers from the influence of the anaesthetic which has been administered **AND**
 - I confirm that conditions/ well-being of the animals will be monitored during the experiment **AND**
 - I confirm that animals with signs of severe distress or pain will be euthanized before the end of the study **AND**
 - I confirm that the following method(s) to be used for sacrificing the animals will not cause unnecessary/ prolonged pain to them
 - cervical dislocation (under anaesthesia or not under anaesthesia)
 - decapitation (under anaesthesia or not under anaesthesia)
 - overdose of anaesthetic
 - carbon dioxide asphyxiation
 - exsanguination under anaesthesia
 - other(s), please specify: _____

Information required in Annex

□ Sample Annex (effective from 1 Nov 2013)

(b) Application for a licence with an “Endorsement to Enable Performance of Experiments Without Anaesthetics” under section 10 of the said Ordinance -

- I confirm that the experiment would necessarily be frustrated by-
- the performance of such experiment under any anaesthetic AND/OR
 - killing the animal on which such experiment is performed before it recovers from the influence of any anaesthetic

Please indicate why-

4. I confirm that the experimental procedures under the type of experiment(s)* and the purpose of experiment(s)* are exactly the same as that of my existing licence under the reference number quoted above AND

- I will not conduct any experiment* after the expiry date of my existing licence under the reference number quoted above until a new licence is issued AND I have been keeping a proper Form 6 in accordance with regulation 4 of the Regulations.

5. I confirm that the experimental procedures under the type of experiment(s)* and the purpose of experiment(s)* are exactly the same as that of my previous licence under the reference number quoted above AND

- I hereby declare that I have not conducted any experiment* after the expiry date of my previous licence under the reference number quoted above AND I have kept a proper Form 6 during the validity period of my previous licence under the reference number quoted above in accordance with regulation 4 of the Regulations.

*“experiment” means any experiment performed on a living vertebrate animal and calculated to give pain (section 2 of the Animals (Control of Experiments) Ordinance, Cap. 340).

Full name**

Contact No.:

HK Identity Card/Passport/Travel Document No.:

Mobile No.:

Email Address :

(Facsimile)



Signed

(Institute/Company chop)***

(Applicant)

** Full name as appears on HK Identity Card/Passport/Travel Document

*** Please obtain an official chop of the Institute/ Company where you are working or studying.

Information required in the New Annex to application form

- **Effective from 1 Nov 2013**
 - ▣ 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 obtain a department chop from an authorized person of the institute/ company, as an endorsement of the application by the institution
 - ▣ To provide personal particulars, for communication and enforcement action

Sample Application Forms

- Please refer to the following link:

< in Word file >

Legal responsibilities of licensee-

To keep Form 6 (Record of Experiments)

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*

Sample Form 6 (Record of Experiments)

ANIMALS (CONTROL OF EXPERIMENTS) REGULATIONS

FORM 6 Record of Experiments

Name of Licensee : _____

Date of experiment.	Place where performed.	Animal used.	Purpose of experiment.	If animal dead, state how died.	Nature of experiments (if performed under teaching permit or under special endorsement this should be stated).

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 arranged 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
 - Heads of Department to seek their assistance in reminding the licensees form 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) (Effective from 1 Nov 2013)

- An Annex will be appended to Form 7 (effective from 1 Nov 2013)
 - ▣ To obtain a department chop from an authorized person of the university/ laboratory/ company in the Annex, as an endorsement of the return by the institution
 - ▣ To provide personal particulars for communication and enforcement action

Sample Form 7 (Return of Experiments)

ANIMALS (CONTROL OF EXPERIMENTS) REGULATIONS
FORM 7
Return of Experiments

Name of Licensee : _____
 No. and date of Licence : _____
 Period covered by return : From _____ To _____


Number of experiments conducted.	Place(s) where performed.	Kinds and number of animals used.	Purpose of experiments (e.g. manual skill, illustrating lectures, etc.).	Any teaching permits, lectures and other endorsements applicable during the period.

Dated _____

Signed _____
(Licensee).

Annex - This section is not part of Form 7 but information supplied would facilitate our processing of your return.

Full name* _____ Contact No.: _____
 HK Identity Card/Passport/Travel Document No.: _____ Mobile No.: _____
 Email Address : _____ (Facsimile): _____
 Name of Institute/Company: _____
 Name of Department: _____


 (Institute/Company chop)**

* Full name as appears on HK Identity Card/Passport/Travel Document
 ** Please obtain an official chop of the Institute/ Company where you are working or studying.

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 is allowed
 - ▣ Inform us in writing of the full address(es) of the new place(s) for experiment
 - ▣ Revised licence superseding the existing one will be issued if approved
- Other proposed changes e.g. change of department/ 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 the year that should cover the period between 1 January of the year and the leaving date

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 http://www.legislation.gov.hk/blis_export.nsf/CurAllEngDocAgent?OpenAgent&Chapter=169.

A Guide to application for licence under the Animals (Control of Experiments) Ordinance

- Please visit the Department of Health website for the latest version of the Guide and Forms
 - http://www.dh.gov.hk/english/useful/useful_alo/useful_alo.htm

Contact Information

- Address:

 - Special Health Services

 - Department of Health

 - Room 79, 21 /F, Wu Chung House

 - 213 Queen's Road East, Wan Chai, Hong Kong

- Tel: 2961 8975

- Fax: 2127 7329

- Email: ro_al@dh.gov.hk

Questions & Answers