

Licensing on Animals (Control of Experiments) Ordinance, Cap. 340



Health Technology and Advisory Division
Department of Health

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1. Background to Cap.340

Animals (Control of Experiments) Ordinance, Cap.340

- To provide for the control of experiments on living vertebrate animals
 - First enacted in 1963
 - Animal – a living vertebrate animal
 - Experiment – any experiment performed on an animal and calculated to give pain



Restrictions on purpose of experiment

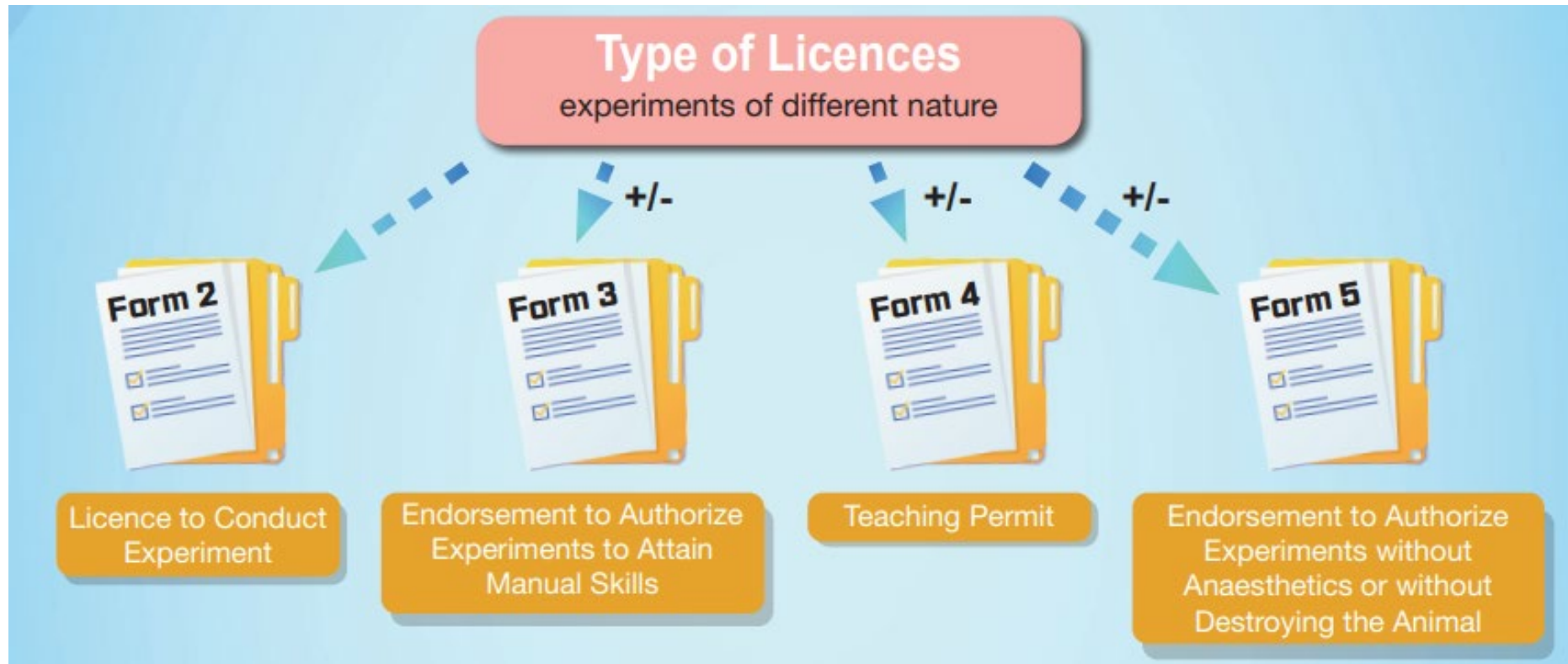
- Section 6(1) - no licensee shall perform any experiment except -
 - a) for the purpose of the **advancement by new discovery of physiological knowledge**, or of any **knowledge** which will be useful for saving or **prolonging life**, or **alleviating suffering**, or for **combating any disease whether of human beings, animals or plants**;
 - b) for the purpose of **testing any former discovery alleged** to have been made **for the advancement of such types of knowledge** referred to in para (a);
 - c) by the order in writing of any judge or district judge in any case where such judge is satisfied that it is essential for the purpose of justice in a criminal case to make such experiment.

To attain manual skill/ for illustration of lectures

- Section 4(1) –
 - ▣ Except under and in accordance with an endorsement made under section 8, no licensee shall perform any experiment for the purpose of attaining manual skill.

- Section 5(1) –
 - ▣ Except under and in accordance with a teaching permit issued under section 9, no licensee shall perform any experiment for the purpose of illustrating any lecture at any academic institution.

Licence, endorsements and permit



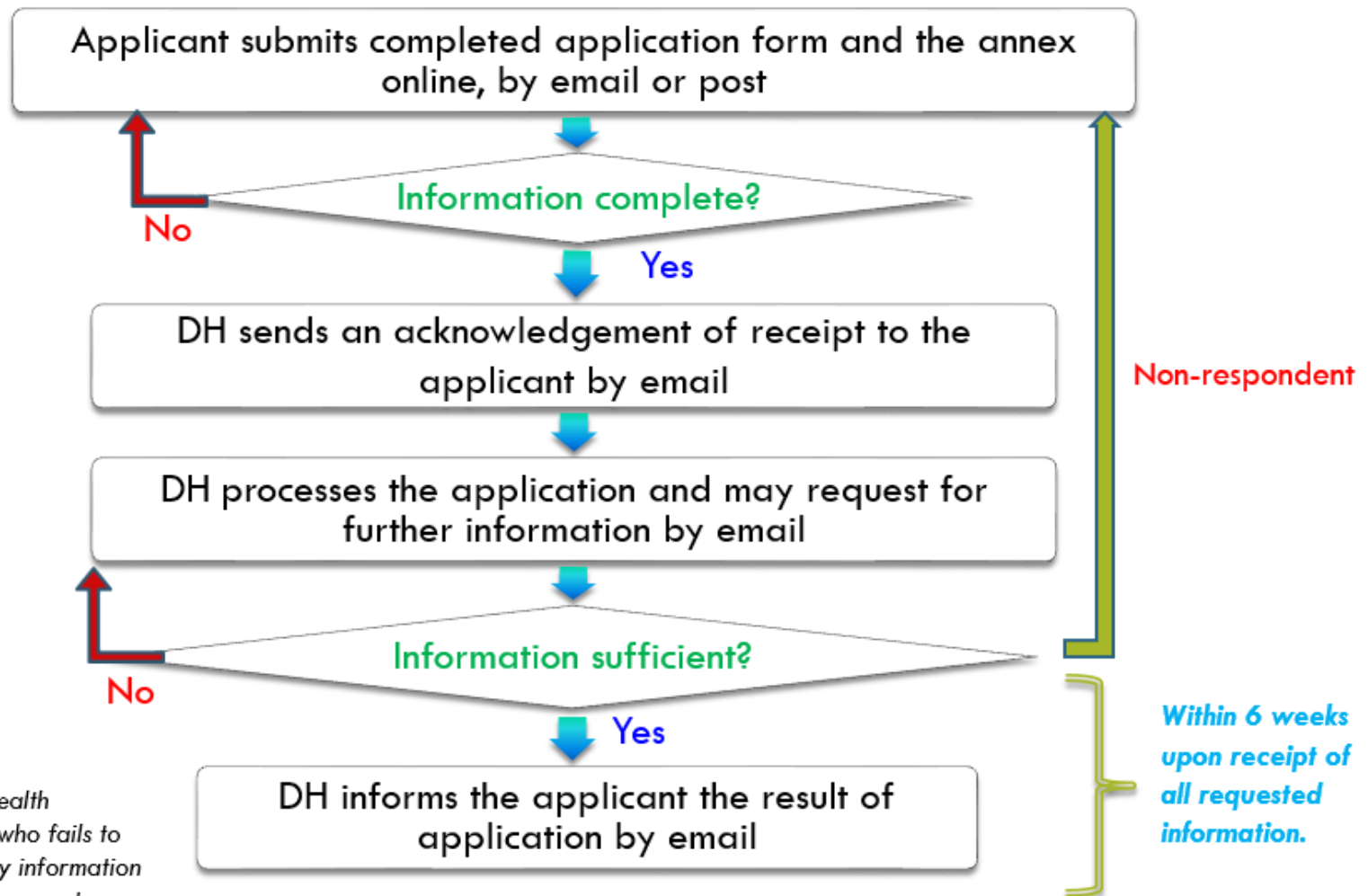
Section 7
Applicable to all
animal experiments

Section 8
E.g. To practice
open heart surgical
techniques using
pigs

Section 9
E.g. To demonstrate
the physiology of
respiratory system
using mice

Section 10
E.g. To study the
efficacy of a newly
discovered analgesic
agent using mice

Application procedures



DH: Department of Health
Non-respondent: one who fails to provide supplementary information before deadline upon request

When filling the application form

Dos

- Read “**Guide to Application**” and “**Notes and Sample Forms**” before filling in the forms
- Include **information specific** to Cap.340:
 - ▣ procedures to be performed on living animals
 - ▣ procedures expected to cause pain to the animals
 - ▣ planned use of anaesthesia, analgesic and/or other pain relieving methods to prevent or minimise pain and suffering expected to cause
- Provide **valid contact information** for communication
- **Check** completeness of the information **before submit**

When filling the application form

Don'ts

- Directly quote/ attach published research article
- Provide lengthy protocol, which is used for purposes other than Cap.340, therefore information is not specific to licence application
- Inclusion of details that is not within the scope of Cap.340, e.g. in vitro analyses
- Lacking the measures to be taken to minimise and/or prevent pain and suffering expected to cause to the animals
- Information provided in Form 1 not tally with that in the Annex, e.g. types of animals, sacrificing methods

Unnecessary or inappropriate information
would prolong the processing time

Requirement for renewal of licence

□ If licensee wishes to:

- Continue with the **same experiment** after the specified periods as stated in the existing licence
- i.e. **no change** of
 - Type of experiment(s); AND
 - Purpose of experiment(s)

□ Licensee should:

- **Check** if the **Type of experiment(s);** AND **Purpose of experiment(s)** are the same as existing licence
- If **no change**, complete the application form, indicate renewal of licence and quote licence ref. no.
- **Submit** application **at least TWO months** before the expiry date of existing licence

- Any change of Type of experiment(s) or Purpose of experiment(s)
→ Require submission of a **NEW** application

Requirement for variation of licence

- If there are:
 - ▣ **changes or additions of place(s)** where the experiment may be conducted
- Licensee should:
 - ▣ **Not perform** the experiment **at the new place(s) right away**
 - ▣ **Inform DH in writing** of the full address(es) of the proposed place(s)
 - ▣ **Receive a revised licence** superseding the existing one if approved
 - ▣ **Perform the experiment at the new place(s)** after receiving the revised licence

It will be **a breach of the Ordinance** to conduct the experiments at a **place other than that specified in the relevant licence.**

Other proposed changes

- e.g. the type(s) of animals, experimental procedure(s) and method(s) used to sacrifice the animals
 - ▣ → Require submission of a NEW application

It will be **a breach of the Ordinance** to conduct the experiments not in accordance with the terms of **the relevant licence**.

Any person who is guilty of an offence under section 3 shall be liable on summary conviction to a **fine at level 1** (HK\$2,000) and to **imprisonment for 6 months**.



2. Legal responsibilities of licensees

- 1) Keep records (Form 6)
- 2) Permit inspections
- 3) Render returns (Form 7)
- 4) Conduct experiment in accordance with terms of licence

1) Keep records (Form 6)

□ Statutory requirement:

- S11(1) of Cap.340 - Every licensee shall **keep**, in such form as may be prescribed, **records** of all experiments performed by him.
- R4 of Cap.340A - Every licensee shall keep **up-to-date** a book in the form as set out as **Form 6** in the Schedule in which he shall **record the particulars** therein indicated of **all experiments performed** by him.

□ Licensee should:

- Keep **up-to-date** records; and
- Record **particulars of all experiments performed** in the form as set out as **Form 6**.
- Records can be in hard-copy or electronic format, provided that:
 - all particulars as listed in Form 6 should be included; and
 - The information is accessible when inspection and to be usable for subsequent reference.

Sample of completed Form 6

Please visit DH website for [Explanatory Notes and Sample forms](#) when filling in Form 6.



https://www.dh.gov.hk/english/useful/useful_forms/useful_forms_ani.html

ANIMALS (CONTROL OF EXPERIMENTS) REGULATIONS

FORM 6
Record of Experiments

Name of Licensee : CHAN Tai Man

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).
01-09-2021	Room 10, 1/F, Lab Building, The University of ABC	20 mice	To study the side effect of Drug A	Overdose of anaesthetic	Research

This should be the same as that stated in licence.

State the date(s) of experiments conducted.

Specify the exact location(s).

Specify the animals used.

This should be the same as that stated in the licence.

Indicate nature of the experiment e.g. research, illustration of lectures (for teaching permit), manual skills (for endorsement) according to the purpose as stated in the licence.

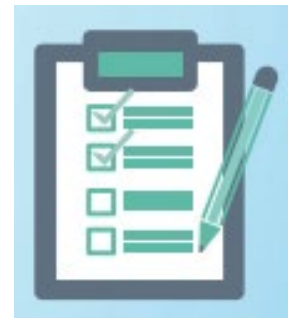
The method(s) used to sacrifice the animals should tally with that as stated in the licence.

2) Permit inspections

- Section 11-

(2) Every licensee shall permit any medical or health officer authorized in writing by the Licensing Authority to **inspect any records** kept by him at any time between 8 am and 6 pm on any day other than a Sunday or public holiday.

(3) Every licensee shall permit any person authorised in writing as aforesaid to **enter and inspect**, for the purpose of securing compliance with the provisions of the Ordinance, any **place** specified in such licensee's licence for the performance of experiments.



3) Render returns (Form 7)

- **Statutory requirement:**
 - S12(1) of Cap.340 - Every licensee shall **render to the Licensing Authority** in such **form** and at such **time** as may be prescribed such returns as may be required in relation to **any experiments performed by the licensee**.
 - R5 of Cap.340A - Every licensee 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 of all experiments performed by him during the **preceding 12 months**.

- Licensee should:
 - **Record particulars of experiments performed** in the preceding 12 months in Form 7;
 - Ensure Form 7 is **accurately filled in** and **signed**; and
 - **Submit Form 7 on or before 1 Jan** each year **on time**.

Sample of completed Form 7

Please visit DH website for [Explanatory Notes and Sample forms](https://www.dh.gov.hk/english/useful/useful_forms/useful_forms_ani.html) when filling in Form 7.



https://www.dh.gov.hk/english/useful/useful_forms/useful_forms_ani.html

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

Name of Licensee : CHAN Tai Man
No. and date of Licence : (20-1) in DH/HT&A/8/2/X Pt-1 01-01-2020
Period covered by return : From 01-01-2020 To 31-12-2020

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.
3	Room 10, 1/F, Lab Building, The University of ABC	20 mice	To study the side effect of Drug A	Nil

Dated 31-12-2020 Signed Chan
(Licensee).

Annex – This section is not part of Form 7 but information supplied would facilitate our processing of your return.
Contact No.: 2345 6789 Mobile No.: 9876 5432
Email Address: abc@abc.com

Remarks (check the box(es) and fill in relevant information if applicable):

I will leave / have left* my School/ Department/ Company in relation to the experiments above with effect from _____ and intend to cancel my existing licence in this return thereafter*

I will stop / have stopped* the experiments above with effect from _____ and intend to cancel my existing licence in this return thereafter*

(Other matters): _____

* please delete as appropriate

Penalty in relation to records and returns

- Any person who contravenes the provisions of:
 - ▣ section 11(1) (Duty to **keep records**) or
 - ▣ section 12 (Duty to **render returns**)

Shall be **guilty of an offence** and shall be liable on summary conviction to a **fine at level 1** (HK\$2,000) and to **imprisonment for 3 months.**

4) Conduct experiment according to the terms of licence

- **Statutory requirement:**
 - ▣ Section 3(2) – No licensee shall perform any experiment except **in accordance with the terms of his licence** and subject to the restrictions imposed by the Ordinance.

- **Licensee should:**
 - ▣ Conduct experiment according to the terms and conditions specified in the licence:
 - **type** of experiment(s)
 - **purposes** of experiment
 - **validity period;** and
 - **place of experiment.**

General penalty

- Any person who is **guilty of an offence** under
 - ▣ section 3 (**performance of experiments only by licensees**);
 - ▣ section 4 (performing experiments to **attain manual skill**);
 - ▣ section 5 (performance of experiments for **illustration of lectures**); or
 - ▣ section 6 (**restrictions upon performance of experiments by licensee**)

Shall be liable on summary conviction to a **fine at level 1** (HK\$2,000) and to **imprisonment for 6 months.**



3. Administration and enforcement of Cap.340

- 1) Inspection conducted by DH
- 2) Monitor submission of returns
- 3) Enquiries or complaints

1) Inspections conducted by DH

- Conduct inspection according to s11 of Cap.340
- Assess the compliance of licensee to the licensing conditions
- Scheduled and/or unannounced inspection visit

- During inspection, authorized officers will:
 - ▣ Check **Form 6** kept by licensee:
 - Whether it is **up-to-date**;
 - **Record all particulars** of experiment performed; and
 - Information recorded **tally with** those on **Form 7** (if applicable)
 - ▣ Check laboratory records in relation to the animal experiment
 - ▣ **Inspect place(s)** for conducting the experiment as specified in the licence.


2) Monitor submission of returns

- Receive and process Form 7
- DH will conduct **inspection** to inspect records kept by **licensee who did not render return**
- **Law enforcement action** will be initiated against licensees who
 - **had conducted experiments**; AND
 - **failed to render** duly completed return **on time** without further notice.



3) Enquiries or complaints

- Any act that may be in contravention of Cap.340 could be reported to the Police directly.
- Alternatively, information in relation to the possible contraventions could be provided to DH.
- If there is reasonable ground to suspect that there may be a contravention of Cap.340, the suspected case would be subject to further investigation or legal advice for prosecution.

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4. Important points to note when collating applications and/or returns for staff/ students

Important points to note

- Submit on time:
 - ▣ Allow sufficient time for collating the applications/ returns so that forms are submitted on time according to the requirement.
- Review:
 - ▣ Check and ensure all the forms are already attached and submitted and nothing is missed during the collation process.
- Keep a copy of email and/or other documents sent:
 - ▣ Serve as a proof
 - ▣ e.g. in case the licensee was suspected failing to render return, the record could serve as a proof that the form has been submitted

Important points to note

- Request for supplementary information/ clarification:
 - ▣ DH may request supplementary information / clarification pertaining to the application/ return during processing, remind applicant/ licensee to provide the requested information within the timeframe to DH.
- Licensee should also keep record of all application documents, including Form 1 and email correspondence (if any), for future reference.
 - ▣ e.g for renewal application, reviewing if any change of procedures, place of experiment, etc



5. Examples of irregularities found during previous inspection

Example (1) – Mistaken licence start date

□ The case:

- From the Form 6 inspected on-site, it was found that animal experiment was performed before the licence granted
- The date of acknowledgement receipt was mistaken as licence start date

□ Contravention:

- **Performing animal experiment without licence (s3)**

□ A person should:

- **Not perform animal experiment** before a licence is granted
- **Check the start day** of the validity of the licence before performing the experiment
- **Perform** experiment only **within the validity period** as stated in licence

Example (2) – Renewal of licence

□ The case:

- Licensee was found to have performed animal experiment before the licence start day
- Licensee assumed renewal licence was continuous without checking the start date of the renewal licence and performed the experiment

□ Contravention:

- **Performing animal experiment without licence (s3)**

□ Licensee should:

- **Submit application** for the same experiment **at least two-month** before end-date if aim to have continuous renewal licence
- **Not assume** renewal licences are always continuous **without gap**
- **Not perform the experiment** until renewal licence is granted
- **Check the start day** of the validity of the licence before performing the experiment

Example (3) – Place of experiments

□ The case:

- Licensee performed animal experiment at a place not specified in the licence
- Licensee explained that, it was not originally planned to perform the experiment at that location, only after granting of licence, the institute further advised certain procedures had to be performed in other location
- Licensee then performed the experiment at the new location

□ Contravention:

- **Performing experiment not in accordance with the terms of licence (s3)**

□ Licensee should:

- **Check the place of experiment in the existing licence** before performing the experiment
- **Inform DH in writing** of the full address(es) of the proposed new place(s) if it is not specified in licence
- **Receive a revised licence** superseding the existing one if approved by DH
- **Perform the experiment at the new place(s)** only after receiving the revised licence

Example (4) – Experimental procedures

□ The case:

- Licensee was found to perform additional procedures on animals which were not included in the licence
- Licensee explained that there was a change of laboratory protocol and therefore the procedures were performed

□ Contravention:

- **Performing experiment not in accordance with the terms of licence (s3)**

□ Licensee should:

- **Check** the information on the **application submitted**, and the **conditions as specified in the respective licence** before starting any new procedures
- **Submit a new application** if there are updates of the procedures
- **Perform** the procedures **after the new licence is granted**

Example (5) – Sacrificing methods

□ The case:

- Licensee was found to use a method for sacrificing the animals which was specified in the licence
- Licensee explained that he was not aware that he did not choose that method during application

□ Contravention:

- **Performing experiment not in accordance with the terms of licence (s3)**

□ Licensee should:

- **Check** the information on the **application submitted**, and the **conditions as specified in the respective licence** before performing the experiment
- **Submit a new application** if there are changes of the experimental procedures
- **Perform** the procedures **after the new licence is granted**

Example (6) – Rendering return

□ The case:

- Licensee was found to have conducted experiment but failed to submit return for previous year
- Licensee explained that a lab manager was responsible for collating and submitting the Form 7 for him
- Upon checking of the record, the respective Form 7 was not attached in the email sent to DH by the lab manager

□ Contravention:

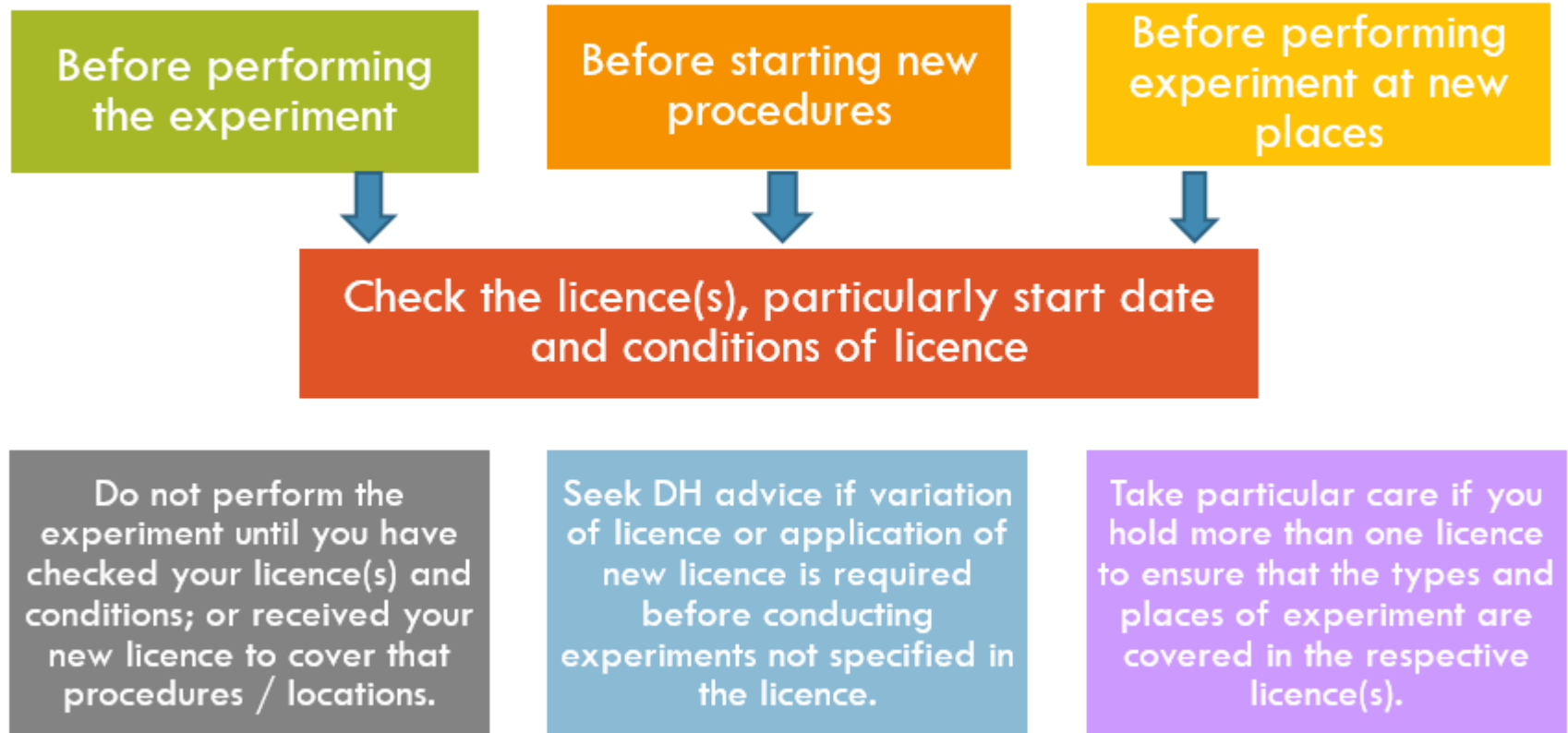
- **Failing to render returns (s12)**

□ Licensee should:

- Be **personally accountable** for failure to submit return on time
- Observe the licensing conditions
- **Ensure relevant forms** are properly **completed and submitted** according to the Ordinance

To avoid non-compliance

A common cause of non-compliance is that the licensee did not check the licence(s) and conditions.



Notes to licensees

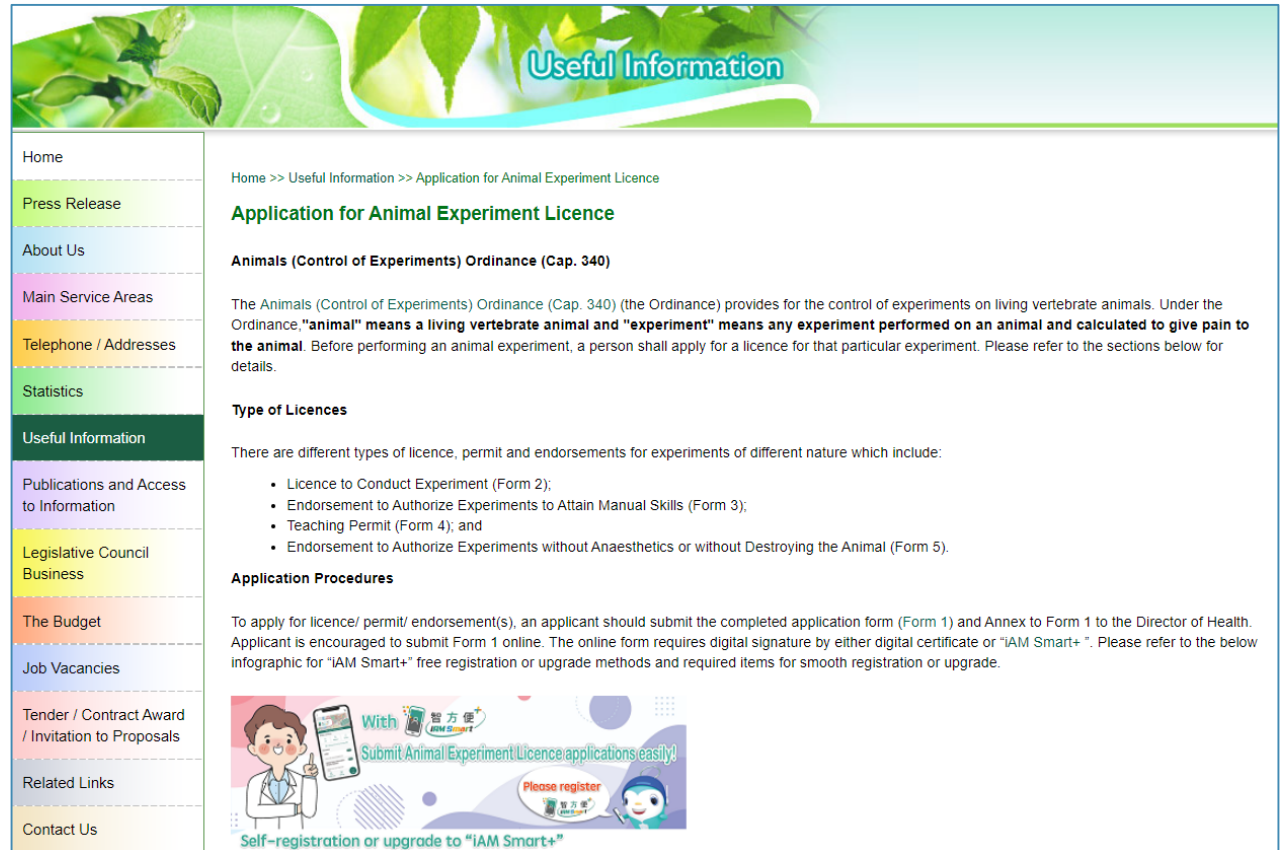
- Licensees are personally accountable for:
 - ▣ keeping experiment records;
 - ▣ submitting returns on time;
 - ▣ observing the licensing conditions; and
 - ▣ performing experiments when valid endorsement or permit is otherwise required.

- Licensee should update DH as soon as possible for:
 - ▣ any change of contact information; or
 - ▣ render return when no more plan to conduct experiment (e.g. leaving corresponding institution).

Useful information for applicants/ licensees

Refer to DH website for the most updated information regarding Application for Animal Experiment Licence

https://www.dh.gov.hk/english/useful/useful_alo/useful_alo.html



The screenshot shows the 'Useful Information' page for the Application for Animal Experiment Licence. The page has a green header with the text 'Useful Information'. Below the header is a navigation menu with the following items: Home, Press Release, About Us, Main Service Areas, Telephone / Addresses, Statistics, Useful Information (highlighted), Publications and Access to Information, Legislative Council Business, The Budget, Job Vacancies, Tender / Contract Award / Invitation to Proposals, Related Links, and Contact Us.

The main content area is titled 'Application for Animal Experiment Licence' and includes the following text:

Home >> Useful Information >> Application for Animal Experiment Licence

Application for Animal Experiment Licence

Animals (Control of Experiments) Ordinance (Cap. 340)

The Animals (Control of Experiments) Ordinance (Cap. 340) (the Ordinance) provides for the control of experiments on living vertebrate animals. Under the Ordinance, "animal" means a living vertebrate animal and "experiment" means any experiment performed on an animal and calculated to give pain to the animal. Before performing an animal experiment, a person shall apply for a licence for that particular experiment. Please refer to the sections below for details.


Type of Licences

There are different types of licence, permit and endorsements for experiments of different nature which include:

- Licence to Conduct Experiment (Form 2);
- Endorsement to Authorize Experiments to Attain Manual Skills (Form 3);
- Teaching Permit (Form 4); and
- Endorsement to Authorize Experiments without Anaesthetics or without Destroying the Animal (Form 5).

Application Procedures











To apply for licence/ permit/ endorsement(s), an applicant should submit the completed application form (Form 1) and Annex to Form 1 to the Director of Health. Applicant is encouraged to submit Form 1 online. The online form requires digital signature by either digital certificate or "iAM Smart+". Please refer to the below infographic for "iAM Smart+" free registration or upgrade methods and required items for smooth registration or upgrade.



The infographic features a cartoon doctor holding a smartphone. Text includes: 'With iAM Smart+ 智方便', 'Submit Animal Experiment Licence applications easily!', 'Please register', and 'Self-registration or upgrade to "iAM Smart+"'. There are also icons for a smartphone and a person.

Forms and documents for reference

Available at DH website https://www.dh.gov.hk/english/useful/useful_forms/useful_forms_ani.html

Name of Form	Form	Personal Information Collection Statement	E-mail	Enquiry
Application Form for the Animals (Control of Experiments) Regulations (Form 1)*	 Online Form			2961 8975
Guide to Application for Licence under the Animals (Control of Experiments) Ordinance				
Record of Experiments (Form 6)				
Return of Experiments (Form 7)*	 Online Form			
Explanatory Notes and Samples of Completed Forms	 Form 1 (New application)  Form 1 (Renewal application)  (Form 6)  (Form 7)			

* The online forms require digital signature by either digital certificate or "iAM Smart+".

- Guide to Application
- Samples of Completed forms

