**HKSTP IACUC Application Form
for External Ethics Approved Use of Live Animals in Research & Development**

*[This form is modified from the original created for public use by the NIH Office of Laboratory Animal Welfare]*

## This part will be completed by HKSTP IACUC:

Proposal #:

Date received:

Approval date:

Expiration date:

PROPOSAL #:

APPROVAL DATE:

EXPIRATION DATE:

P POSAL #:

ROPOSAL #:

PROPOSAL #:

APPROVAL DATE:

EXPIRATION DATE:

**Important:** This form shall be completed by the **principal investigator or staff in-charge** of the proposed project. Before completing this form, please read the **“HKSTP IACUC Handbook” (“Handbook”)** in the IACUC webpage which can be accessed through the following link <https://www.hkstp.org/what-we-offer/institute-for-translational-research/hkstp-institutional-animal-care-and-use-committee-iacuc/>

Before a company is to start using (including housing or breeding) **any type of** **live animals** for any of its new/revised/extended R&D activities, the company is responsible for obtaining ethics clearancefor such proposed activities, to ensure appropriate ethical standards will be upheld for animal care and use. The **ethics standards and guidelines** listed in the Handbook must be complied with at all times.

Please complete all sections in wordings that are understandable to a lay person. Expand the text boxes as you type. Mark all applicable boxes. Enter “N/A” if a section is not relevant, instead of leaving it blank.

Submit (1) this form, (2)\* copy of external ethics approval letter, (3)\* application form for external ethics approval, (4) valid license issued by the HKSAR Department of Health for all personnel involved in animal handling, (5) other relevant attachments to the IACUC Secretariat at iacuc@hkstp.org

**\*either (2) or (3) must indicate the specific location(s) of the use of animals in HKSTP**

……………………………………………………………………………………………………………

|  |  |
| --- | --- |
| **Project title:** |  |

[ ]  New submission **with** external ethics approval

[ ]  Extension of \_\_\_\_ years \_\_\_\_ months for approved project (HKSTP IACUC ref. no.: \_\_\_\_\_\_\_\_\_\_\_\_)

[ ]  Amendments in Section(s): [ ]  Project title [ ]  A [ ]  B [ ]  C [ ]  D [ ]  E [ ]  F [ ]  G

 [ Notes:Pleasehighlight amendments in subsequent sections in yellow. ]

Is this a sponsored trials/ study?

[ ]  Yes (name of sponsor: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_)

[ ]  No

#### COMPANY & PERSONNEL INFORMATION

|  |  |
| --- | --- |
| 1. Company name:
 |  |
| Affiliated technology cluster or program in HKSTP: | ☐ Biomedical Technology ☐ Electronics ☐ Green Technology ☐ Information & Communications Technology ☐ Material & Precision Engineering☐ Incu-Bio ☐ Incu-Tech ☐ Incu-App ☐ Other program: \_\_\_\_  |
|  | ☐ Health@InnoHK ☐ AIR@InnoHK  |
| Location(s) in HKSTP premises:(Building # & unit #) |  |

1. Principal investigator or staff in-charge of this project:

|  |  |  |  |
| --- | --- | --- | --- |
| **Name**(Please underline the surname) | **Position & department in the company** | **Direct phone number** | **Email address** |
|  |  |  |  |

1. All other personnel (including co-investigators, interns) that are authorized to conduct procedures involving live animals in this proposal:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Name**(Please underline the surname) | **Role in this project** | **Position & department in the company** | **Direct phone number** | **Email address** |
|  |  |  |  |  |
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**Important:**

 All personnel listed in (2) & (3) above shall:

 (i) Complete the training on 3R principles listed on the **Application Checklist** (or equivalent training).

 (ii) Provide a copy of the **valid license/permit/endorsement** under *Animals (Control of Experiments) Ordinance* (Cap. 340)
to HKSTP IACUC, if this project will involve live non-human vertebrate animals. Refer to the HKSARG Department of Health website for license application form and reporting guide: <https://www.dh.gov.hk/english/useful/useful_alo/useful_alo.html>

 (iii) Apart from complying with the **research standards & guidelines** listed in the Ethics Guide, you should also refer to the **AAALAC “Guide for the Care and Use of Laboratory Animals”** ([8th ed.](https://www.aaalac.org/the-guide/)) for general principles and ethical considerations.

#### ANIMAL REQUIREMENTS

**Ref: For this and subsequent sections, please also refer to the following references whenever necessary:**

* 1. AAALAC Guide for the Care and Use of Laboratory Animals (8th ed.) [(NRC, 2011)](https://www.aaalac.org/the-guide/)
	2. The Design of Animal Experiments: Reducing the Use of Animals in Research through Better Experimental Design (2nd ed.) ([SAGE, 2016](https://books.google.com.hk/books?id=dpzPjwEACAAJ))
	3. Principles of Experimental Design for the Life Sciences ([CRC Press, 1996](https://books.google.com.hk/books/about/Principles_of_Experimental_Design_for_th.html?id=rZS6kVvPV9kC))
	4. Statistics and Experimental Design for Toxicologists (4th ed.) ([CRC Press, 2005](https://books.google.com.hk/books?id=RRmx7RMtvukC))
	5. Statistics for Experimenters: Design, Innovation, and Discovery (2nd ed.) ([Wiley, 2005](https://books.google.com.hk/books?id=oYUpAQAAMAAJ))
	6. Experimental Design for Biologists ([Cold Spring Harbour Laboratory Press, 2007](https://books.google.com.hk/books?id=ksu2jWWF3k0C))
1. Animals that will be used:

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Genus***[eg. Mus]* | **Species***[eg. musculus]* ***/* Common name***[eg. Black6]* | **Strain/sub-species/breed***[eg. C57BL/6]* | **Approx. age,weight or size** | **Sex** | **Number of animals to be used each year:** | **Total number in the 3 years** |
| **Year 1** | **Year 2** | **Year 3** |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
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|  |  |  |  |  |  |  |  |  |
|  |  | **Total number of animals to be used in this project =**  |  |

|  |  |
| --- | --- |
| 1. Bacteriological status:*[eg. germfree (axenic), defined flora (gnotobiotic), specific pathogen free (SPF), conventional]*
 |  |
|  |
| 1. Viral status:*[eg. simian immunodeficency virus, simian retrovirus]*
 |  |
|  |
| 1. Source(s) of animals:*[eg. name of vendor or breeder, or bred in-house]*
 |  |
| **Note:** Please provide a copy of animal health certificate(s) if available.  |
|  |
| 1. Primary animal housing location(s):*[eg. Building number & unit in HK Science Park (HKSP). If outside HKSP, include name of campus.]*
 |  |
| 1. Location(s) where manipulation and subsequent care will be carried out:
 |  |
| **Note:** The PI/staff in-charge named in **Section A2** must certify in **Section H** that the facilities/locations listed in (5) & (6) above have the resource capability to support this proposed project. |

#### TRANSPORTATION

Transportation of live animals must conform to all international guidelines/policies and local regulations.

Please ensure animals will be secured in their well-covered containers (if applicable) during transportation within a facility, between facilities on the same campus, or on public roads to/from locations in this study.

HKSTP Facilities Management Office will provide companies with site operation procedures for animal delivery and routing in buildings. Should you require transportation of animals in and out of premises or between HKSTP facilities, please contact HKSTP Facility Management Office directly at 2639 8008 for the relevant guidelines.

[ ]  I acknowledge the above.

#### STUDY OBJECTIVES

Briefly explain the aim of the study and why the study is important to human or animal health, the advancement of knowledge, or the good of society in language that a layperson can understand.

#### DESCRIPTION OF EXPERIMENTAL DESIGN AND ANIMAL PROCEDURES

1. Types of experiments/procedures:

Short-term: Procedures will be finished within 24 hours. There is no holding of animals after 24 hours:

[ ]  Euthanasia only
[ ]  Experiments performed wholly under anesthesia followed by termination of the animals [ ]  Experiments on conscious animals followed by termination of the animals

Long-term: [ ]  Experiments on conscious animals

[ ]  Experiments on conscious animals with period(s) of anesthesia

Breeding: [ ]  Animals to be bred by the Principal Investigator and to be used for subsequent R&D

1. Specify the **experimental endpoint criteria.** List the criteria that will be used to determine when euthanasia is to be performed. Death as an endpoint must be scientifically justified. *[eg. tumor size, percentage body weight gain or loss, inability to eat or drink, behavioral abnormalities, clinical symptomatology, or signs of toxicity]*
2. Specify the **humane endpoint criteria**. How does this differ from the experimental endpoint criteria.
3. Will the study involve surgery?

|  |  |
| --- | --- |
| [ ]  Yes | [ ] No |

1. Types of anesthesia, analgesia, transquilization and other agents used in the study.
2. Method of euthanasia/ disposition of animals at end of study.

#### BIOLOGICAL MATERIAL/ANIMAL PRODUCTS FOR USE IN ANIMALS

*[eg. cell lines, antiserum, etc.]*

1. Please complete the following table:

|  |  |  |  |
| --- | --- | --- | --- |
| **Specify each biological material/animal product** | **Source** | **Material Sterile or Attenuated** | **Has the material been tested for pathogens?** (eg. *MAP - Mouse Antibody Production; RAP - Rat Antibody Production; HAP - Hamster Antibody Production, PCR test)* |
| **No** | **Yes** | **No** | **Yes***[Attach copy of test results]*  |
|  |  | [ ]  | [ ]  | [ ]  | [ ]  |
|  |  | [ ]  | [ ]  | [ ]  | [ ]  |
|  |  | [ ]  | [ ]  | [ ]  | [ ]  |
|  |  | [ ]  | [ ]  | [ ]  | [ ]  |
|  |  | [ ]  | [ ]  | [ ]  | [ ]  |
| 1. I certify that the tested materials to be used have not passed through rodent species outside of the animal facility in question and/or the material is derived from the original tested sample. To the best of my knowledge the material remains uncontaminated with rodent pathogens.
 |
|  |  | **Initials of Principal Investigator** |

#### HAZARDOUS AGENTS

 Ref: Please refer to the following:

1. HKSTP Safety, Health, and Environment (SHE) Handbook
2. Occupational health and safety in the care and use of research animals, NRC, USA (1997)
3. Biosafety in microbiological and biomedical laboratories, CDC (2009)
4. The study will be conducted at Animal Biosafety Level (ABSL): [ ]  1 [ ]  2 [ ]  3 [ ]  4

*Currently not allowed**at Hong Kong Science Park*

1. Please complete the following table:

|  |  |  |  |
| --- | --- | --- | --- |
| **Hazardous Agent** | **No** | **Yes** | **If yes, specify the agent.** **Also state the ref. no. of any past HKSTP IACUC application that has the agent approved**(Mark “N/A” if not applicable) |
| *Example:**Hazardous chemicals or drugs* | [ ]  | [x]  | 1. *5-bromo-2'-deoxyuridine*
2. *Tamoxifen (HKSTP-IACUC-2020-XXXX)*
 |
| Hazardous chemicals or drugs | [ ]  | [ ]  | 1.
2.
 |
| Biological agents | [ ]  | [ ]  | 1.
 |
| Recombinant DNA | [ ]  | [ ]  | 1.
 |
| Radionuclides | [ ]  | [ ]  |  |
| Others | [ ]  | [ ]  |  |

1. Describe the practices and procedures required for the safe handling and disposal of contaminated animals and material associated with this study. Also describe methods for removal of radioactive waste and, if applicable, the monitoring of radioactivity.
2. Additional safety considerations:

#### CERTIFICATIONS BY PRINCIPAL INVESTIGATOR / STAFF IN-CHARGE

I, the undersigned, who has authority to make this declaration on behalf of my company and to bind the company to the matters stated in this form, hereby certify as follows:

1. All the information stated in this form are true, complete and accurate.
2. I have determined the proposed project is not unnecessarily duplicative of previously reported research.
3. I shall take reasonable care to ensure that the proposed work/experiment(s) is conducted in accordance with the best modern practice and in such a way so as to safeguard the welfare of and minimise the pain suffered by the animals involved. I assure that measures to be taken to minimise animal suffering/injury are the most humane and compatible with the objectives of the work/experiment.
4. I have completed the requisite training course or any equivalent courses (please refer to the **Application Checklist**) and all other necessary investigator training courses required by my company.
5. The individuals listed in **Section A** that will conduct procedures involving animals in this proposal have completed the requisite training course, and have received training in:
* the biology, handling and care of the species to be used in this proposal;
* applying aseptic surgical methods and techniques (if necessary);
* the concept, availability and use of research or testing methods that limit the use of animals or minimize distress;
* the proper use of anesthetics, analgesics and tranquilizers (if necessary); and
* the procedures for reporting animal welfare concerns.
1. I will ensure that facilities, safety equipment and procedures are in place to enable this proposed work to be carried out safely.
2. I will obtain approval from the HKSTP IACUC before initiating any changes in this project.
3. I will notify the HKSTP IACUC regarding any unexpected study results that impact the animals. In addition, any unexpected incidents, as well as unanticipated pain or distress, morbidity or mortality will be documented and reported to the attending veterinarian for this project and also the HKSTP IACUC.
4. I am familiar with and will comply with the **“HKSTP Ethics Guide for Animal Research”**, including the research ethics standards and guidelines that are referred at **point 2** of the guide, as well as all pertinent rules, policies and regulations of HKSTP as the same may be updated from time to time.
5. I am familiar with and will comply with all applicable guidelines and regulatory and statutory requirements of the Hong Kong Special Administrative Region.
6. I further understand that if any information provided in this application is false or if I or my team fail to adhere to any of the ethics guide and requirements referred at **(9) and (10)** **above** (“Requirements”), HKSTP reserves the right to demand that part/all of the activities in this project be ceased without any liability whatsoever towards my company. In the event of any serious violation of the Requirements, HKSTP may, at its absolute discretion, terminate my company’s lease with HKSTP.

**Principal Investigator / Staff in-charge:**

[The name below should match that in **Section A2**. Electronic signature is acceptable.]

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Name: |  | Signature:  |  | Date: | Click or tap to enter a date. |

#### CONCURRENCES

Concurrence of resource capability in the indicated facility/location to support the proposed study:

I/We hereby endorse this application and confirm that the principal investigator / staff in-charge named in **Section A2** is appropriately experienced in the work proposed and that the company has adequate facilities (listed in **Section B5 – B6**) for the experiment(s)/procedures to be conducted safely and in such a way as to safeguard the welfare of and minimise the pain suffered by the animals involved.

*Supervisor/person in-charge of managing the facility/location to be used in this project:*

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Name: |  | Role: |  | Signature:  |  | Date: | Click or tap to enter a date. |

*Supervisor/person in-charge of managing the facility/location to be used in this project:*

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Name: |  | Role: |  | Signature:  |  | Date: | Click or tap to enter a date. |

#### FINAL APPROVAL

 *(This part will be completed by HKSTP IACUC)*

Certification of review and approval by the HKSTP Institutional Animal Care and Use Committee (IACUC):

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Name: |  | Role: |  | Signature:  |  | Date: | Click or tap to enter a date. |