HKSTP IACUC

01 – Compliance Policy

Version History

Version	Effective Date
1	28/02/2023

1. Purpose

HKSTP IACUC is committed to the highest standards of integrity, respect, and ethics for humane treatment of animals in research as governed by the International Guiding Principles for Biomedical Research Involving Animals, HK Code of Practice for Care & Use of Animals for Experimental Purposes, EU Directive 2010/63/EU on the Protection of Animals Used for Scientific Purposes.

The purpose of this policy is to set out the obligations and practical requirements to all animal research projects within HKSTP to ensure ethical standards and guidelines on animal welfare management are followed. All animal research projects on HKSTP premises involving the use of Live non-human vertebrates, including independently feeding larval forms, embryos and fetal forms of mammals and non-mammals or live cephalopods are required to obtain HKSTP IACUC ethics approval or acknowledgment before project commencement / revision / extension. **HKSTP IACUC Handbook focuses primarily on the use and care of rodents, researchers are responsible to conduct species-specific research when designing their protocol. Guidelines on ethics-related matters for use of other animal species will be reviewed by HKSTP IACUC on case-by-case basis.**

2. Scope

The policy applies to all research protocols and personnel involved in the handling of animals for research purposes within the premises of HKSTP.

Animals requiring ethics approval include the followings:

i. **live non-human vertebrates**, including

   a. their independently feeding larval forms; and

   b. embryos and fetal forms of mammals and non-mammals from the last third of their normal development.

ii. **live cephalopods**

3. Responsibilities and Authorities

Innovative technology impacts human and animal healthcare. Companies in this industry often face a range of complex ethical choices during product research and development (R&D) that are part of

their business decision-making. Since research ethics governs the standards of conduct for scientific researchers, demonstrating ethical practices in research reflects the research integrity of a company and can enhance its reputation in the industry.

Compliance to research ethics can often smooth the path to regulatory approval and market adoption for a product. Moreover, it can be an enabling factor for the company when considering to working with other (especially larger) corporations and investors in the future.

It is in the best interest of companies to take proactive measures in all stages of R&D to ensure that high standards of research ethics are maintained. It is the responsibility of companies to comply with research ethics standards and guidelines, including, without limitation the followings:

i. International Guiding Principles for Biomedical Research Involving Animals (2012) https://olaw.nih.gov/sites/default/files/Guiding_Principles_2012.pdf

ii. HK Code of Practice for Care & Use of Animals for Experimental Purposes (2004) https://www.afcd.gov.hk/english/aboutus/abt_adv/files/Code_of_Practice_Care_and_Use_of_Animals_for_Experimental_Purposes_English.pdf

iii. EU Directive 2010/63/EU on the protection of animals used for scientific purposes https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:276:0033:0079:EN:PDF

4. Alternate Animal Use

The principles of the 3Rs; Replacement, Reduction and Refinement should be followed in the experimental design of research projects.

Replacement – Methods which replace animals of a higher life form with those of a lower life form or avoid the use of animals and employ alternative methods to achieve the same objectives as experiments which use animals.

Reduction – Methods which minimize the number of animals used per experiment to obtain the necessary data that support the scientific objectives.

Refinement – When laboratory animals must be used, the minimization as far as possible of the frequency of use of inhumane methods or of the degree of harm caused.

In accordance with scientific principles, research into and application of laboratory animal alternatives shall be actively pursued. Unnecessary duplication of animal experiments shall be avoided.

4.1 The number of animals used shall be reduced to a minimum. The entry of unauthorized personnel to places where experiments are conducted shall be avoided.

4.2 When surgery or dissection is carried out on live animals, including when neuromuscular blockers are used, effective anesthesia shall be performed. Survival surgeries shall be conducted using aseptic techniques. During postoperative recovery, analgesics, appropriate nursing care, and dietary adjustments shall be provided based on the animal's condition.

4.3 Restraint of animals shall be carried out in a way that as far as possible reduces their discomfort, suffering, and stress responses. Restraint devices shall be of appropriate structure, size, and durability, and be safe, hygienic and easy to use. Physical restraint shall be used to the minimal extent required to meet the experimental objectives.

4.4 Laboratory animal husbandry, facility management, experimental procedures including the determination of humane endpoints and euthanasia for each species, environmental controls, and execution of all laboratory animal experiments should comply with laboratory animal welfare and ethics quality standards, management regulations. PI is required to develop a Standard Operating Procedures (SOP) for the specific research project and animal of use. The SOP should be provided to HKSTP IACUC for inspection and supervision during implementation.

4.5 Animals shall be killed using appropriate methods of euthanasia. No other animals should be present where killing is being carried out. Only after death is confirmed shall an animal's cadaver be disposed of appropriately.

4.6 Provided the experimental results have been obtained, a "humane endpoint" shall be selected at the first opportunity, reducing as far as possible the time the animal experiences suffering. With the exception of rare instances when the experiment requires it, death (except by means of euthanasia) should not be used as a study endpoint.

4.7 Wild animals that have not been adversely affected by an experiment and are no longer needed, for example those used in a control group, may be returned to their original habitat in accordance with the law once they have undergone a scientific examination and assessment.

5. Procedures

5.1 Partner companies in HKSTP premises are required to undergo research ethics review and obtain clearance prior to starting any animal research activities (including any housing of animals that will be used in its research activity).

5.2 Ethics clearance of any **new / revised / extended study** is required to ensure appropriate ethical standards are being upheld for animal care and use.

5.3 An ethics clearance is normally in the form of an ethics approval or exemption that is provided/acknowledged by an independent animal research ethics committee (AEC) or institutional animal care and use committee (IACUC), after the relevant committee has carried out ethics review of the research study. The peer review process of ethics review is to ensure a proper balance between innovation and ethics.

5.4 To apply for ethics review and clearance from HKSTP IACUC, the applicant may select one of the following channels.

i. **For new applications**

Submit the following documents in one email to iacuc@hkstp.org with the name of your company in the email subject:

a. Completed application form

b. Completed application checklist

c. The required supporting documents stated in the application checklist**

**All the project personnel in any animal-use project should be in full compliance with HKSAR's law, including (if applicable) but not limited to obtaining the corresponding license issued by the HKSAR Department of Health. If any personnel's license is still pending as of the HKSTP IACUC application deadline, the principal investigator may still submit an application set for the project before the deadline to HKSTP IACUC for initial review, and submit the outstanding license copy to HKSTP IACUC once available. However, the HKSTP IACUC will only grant a decision for the project after all the required documents have been reviewed.

Relevant materials can be accessed via: https://www.hkstp.org/what-we-offer/institute-for-translational-research/hkstp-institutional-animal-care-and-use-committee-iacuc/

ii. **For applications with external ethics approval**

If a company collaborates with an external organization/ institution that has an AEC/IACUC. The study's Principal Investigator (PI) may choose to apply for site extension from the external AEC/IACUC to cover the part of the study that is conducted in HKSTP premises.

For such projects that will be conducted on HKSTP premises, please submit the following documents in one email to iacuc@hkstp.org with the company name in the email subject.

a. Completed application form (with external ethics approval)

b. A copy of the external ethics approval letter**

c. A copy of the animal use protocol that was submitted to the external IACUC/AEC for review**

d. A copy of the valid license of all the personnel that will handle the live animals in the project, which was issued by the HKSAR Department of Health under Animals (Control of Experiments) Ordinance (Cap. 340)

e. A list that shows the maximum estimated number of animals that will be used for the project in HKSTP premises at any time, as well as the total number of animals

**Either (ii) or (iii) shall indicate the specific location(s) of the use of animals in HKSTP.

Relevant materials can be accessed via: https://www.hkstp.org/what-we-offer/institute-for-translational-research/hkstp-institutional-animal-care-and-use-committee-iacuc/

5.5 All procedures performed by the company shall be in accordance with the protocols approved/ acknowledged by HKSTP IACUC.

5.6 If any ethics approval from HKSTP IACUC is suspended or withdrawn, the company must immediately cease all relevant animal research activities.

5.7 For acknowledged applications with external ethics approval, if any ethics approval from the external AEC/IACUC is suspended or withdrawn, the company must immediately cease all relevant animal research activities.

5.8 To facilitate a company's ethics and regulatory compliance, the company is required to acknowledge and agree for representatives from an AEC/IACUC and/or the relevant government department(s) to have a right by prior appointment and arrangement to conduct periodic inspection/monitoring visits at the company's animal housing and laboratory areas. The company shall provide all assistance in relation to such visits, including allowing access of the relevant areas to such representatives and provide relevant information as may be requested.

5.9 An ITR company must declare and provide the following information to HKSTP during tenancy/program application and progress update/review.

i. Declare whether its tentative, planned or on-going R&D activities during its tenancy/program period involve animal research or not, including those that will take place / have taken place:

    a. in HKSTP premises, and/or
    b. elsewhere in Hong Kong, if related to the company's R&D in HKSTP premises

ii. If yes, complete the checklist at the "Ethical Considerations" section on the form, and

iii. Provide supporting documents for each animal research study for compliance as follows:

    a. If any part of the study will be done in HKSTP premises: submit of a copy of the relevant ethics clearance or submit an application to HKSTP IAUC for review (subject to approval) is <u>mandatory</u>.

    b. If any part of the study will be done outside of HKSTP premises: Submission of a copy of the relevant ethics clearance is <u>recommended</u>.

5.10 A company to be moved in to HKSTP premises under the InnoHK project (an "InnoHK company") shall declare and provide the following information on or prior to its moving in to its HKSTP premises and thereafter on each anniversary of its lease of the relevant premises as an update.

i. Declare whether its tentative, planned or on-going R&D activities during its tenancy/program period involve animal research or not, including those that will take place / have taken place:

    a. in HKSTP premises, and/or
    b. elsewhere in Hong Kong, if related to the company's R&D in HKSTP premises

ii. If yes, complete the checklist at the "Ethical Considerations" section on the form, and

iii. Provide supporting documents for each animal research study for compliance as follows:

a. If any part of the study will be done in HKSTP premises: submit of a copy of the relevant ethics clearance or submit an application to HKSTP IAUC for review (subject to approval) is mandatory.

b. If any part of the study will be done outside of HKSTP premises: Submission of a copy of the relevant ethics clearance is recommended.

5.11 If deemed necessary by HKSTP, a company shall provide further proof of ethical appropriateness of its R&D activities.

6. Animal Facility Inspection

6.1 Partner companies must agree to the animal facility inspections announced by the approval body. The animal facility inspection is carried out by the approving body of the specific protocol. Research personnel or facility supervisor of the application is required to be present during the animal facility inspection.

6.2 All protocols approved by HKSTP IACUC (excluding site extension applications) must comply with the animal facility inspections conducted by IACUC on semi-annual basis. The inspection shall include the details of implementation of projects that involve laboratory animals; animal housing conditions; operation and safety of facilities; hygiene, disease control and prevention; condition of cages and other equipment; housing density; animal health; environmental enrichment; compliance with standards of experimental procedures and surgery; occupational health of the staff and bio-safety; and implementation of laboratory animal welfare and ethics standards.

Animal facility site survey shall be conducted by IACUC prior application approval, when determined necessary, for the purpose to ascertain, without limitation, the facilities and environment within the Company's premises to be suitable for conducting animal research as set out in the application submitted.

6.3 HKSTP IACUC has delegated the following authority to its animal facility inspection team;

i. Contact research personnel or facility supervisor of the application to discuss arrangements for the animal facility inspection;
ii. Identify any non-compliance areas and provide recommendations for compliance;
iii. Evaluate the severity of non-compliance;
iv. Maintain a compliance log of all non-compliance;
v. Assist to resolve serious and regular non-compliance events by working with the laboratory or facility involved in the non-compliance;
vi. Report non-compliance events and follow up actions to HKSTP IACUC;
vii. Identify chronic non-compliance;

viii. Monitor non-compliance report resolutions and provide regular updates to HKSTP IACUC on their activities

7. Allegations

7.1 Any allegation of non-compliance should be reported to HKSTP IACUC via telephone: (852) 2629 0190 or email: iacuc@hkstp.org

7.2 An allegation of non-Compliance may come from various sources inside or outside HKSTP, or an anonymous source.

7.3 Named or anonymous reports can be made without concern about reprisals or dismissals. All reports will be taken seriously and impartially examined by the HKSTP IACUC at its best effort.

7.4 Upon receipt of an allegation, HKSTP IACUC will take the necessary procedures to assess the risk and the reasonability of the allegation. A reasonable allegation is one that is made in good faith and falls within the scope of HKSTP IACUC.

7.5 The ability of HKSTP IACUC to investigate an allegation may be hampered if it is from an anonymous source, or if an allegation is not made in writing, and in some cases HKSTP IACUC may be unable to proceed.

7.6 HKSTP IACUC will investigate the allegation through means deem appropriate under the circumstances.

7.7 Upon any conflict of interest, if any member of HKSTP IACUC are in conflict of interest with the allegation, they will be excluded from the inquiry and/or investigation.