ANIMAL CARE AND USE PROTOCOL

Mahidol University-Institute Animal Care and Use Committee (MU-IACUC)

COVER SHEET
Aquatic Animals Study Protocol

Protocol number		This section will be completed by the MU-IACUC
Received by IACUC (dd/mm/yy)		
Approved/Request modification (dd/mm/yy)		
Resubmitted (dd/mm/yy)		
Approved/Disapproved by IACUC (dd/mm/yy)		
Approved/Disapproved by Dean (dd/mm/yy)		
Expiration Date (dd/mm/yy)		

Protocol title:
(Thai)……..……....
.....
(English)……...
…….…

If this protocol is a part of the main project, please provide the main project title:
(Thai) .....
(English) .....
Funding source(s): .....
Grant proposal: ☐ to be submitted
☐ has been submitted
☐ has been approved. If approved, duration of approval .....

Anticipated protocol period: From ..... **To** .....

Type of animal protocol
[ ] Research: In the Field of .....
[ ] Testing/Monitoring (please specify) .....
[ ] Teaching: Course Title/Level .....
[ ] Biological Production: (please specify) .....
[ ] Animal Breeding (please specify) .....
[ ] Other (please specify) .....

Principal investigator: Name……..…

(for a student thesis, the principal investigator is the principal adviser, and the student is a co-investigator)

Position: ……**Department** ……...……

Faculty/Institute ……...

…….

Tel. ……**Fax.** ….……

E-mail ……....

* **Animal use license no……Expired date…….**

Co- investigator: Name ……...…….

Position: ……**Department** ……...……

Faculty/Institute ……....

…….

Tel. ……**Fax.** ….……

E-mail ……....

***Animal use license no……Expired date…….**

Co- investigator: Name ……...……

Position: ……**Department** ……...……

Faculty/Institute ……....

……

Tel. ……**Fax.** ….……

E-mail ……....

***Animal use license no……Expired date…….**

Contact person in case of emergency: .....
Office/Affiliation: .....
Phone: .....**E-mail:** .....

**Issued by Institute of Animal for Scientific Purposes Development, NRCT*

Your signature as P.I., Co-investigator on this application verifies that the information herein is true and correct and that you are familiar with and will comply with standard of animal care and use established under the ethical guidelines and policies of the Mahidol University and Office of the National Research Council of Thailand **(**NRCT) and the animal for scientific purpose act., B.E. 2558

Principal investigator: Name……..…

_____ _____
(Signature) (Date)

Co- investigator: Name ……...… ……

_____ _____
(Signature) (Date)

Co- investigator: Name ……...… ……

_____ _____
(Signature) (Date)

Head of department: Name ……...……

_____ _____

(Signature) (Date)

Faculty/Institute: ……

……..……

****

This section will be completed by the MU-IACUC

Statistical review: Name …… …….……

_____ _____
(Signature) (Date)

Safety review: Name …… ……..……

_____ _____
(Signature) (Date)

Attending veterinarian: Name …… ……..….....…

* Animal use license no……Expired date……

* * Veterinary practitioner license no……..……Expired date…….

_____ _____
(Signature) (Date)

** Issued by Institute of Animal for Scientific Purposes Development, NRCT*

*** Issued by The Veterinary Council of Thailand*

Approval

MU-IACUC Review:

☐Approved ☐Approval recommended ☐Disapproved

……..……

(Chair, MU-IACUC signature, Date)

MAHIDOL UNIVERSITTY
STANDARDIZED RESEARCH PROTOCOL FORMAT FOR PERMISSION OF ANIMAL CARE AND USE
(Aquatic Animals Study Protocol)

1. Non-technical summary: *(Provide a brief description of the project that is easily understood by non-scientists, expressing its significance and needs for undertaking the study).*

……
……

2. Rationale and literature review: *(Include a brief statement of the requirement for the information being sought. Typically, the literature or the experience that led to the proposal will be briefly reviewed, references cited will be provided).*

……
……

3. Literature search for duplication: *(This search must be performed to prevent unnecessary duplication of previous experiments).*

3.1 Literature source(s) searched *(database name)*:……..

3.2 Date of search: *(perform the search no earlier than 6 months prior to IACUC meeting, **(dd/m/yy)***……

3.3 Period of search *(range of years searched):*……..

3.4 Key words used in search: ……

3.5 Results of search: Does the proposed research duplicate any previous work?

☐ No ☐ Yes

If YES, explain why it is scientifically necessary to duplicate the experiment.

……

4. Objective(s): *(Provide goal/specific aim of this project)*

……
……

5. Experimental design: *(Provide a complete description of what will be done to the animals. Succinctly outline the formal scientific plan and direction for experimentation, sequential description of procedures what will be done to the animals from obtain the animal to the end of study. A diagram or chart may be helpful to explain complex design).*

……
……

6. Data analysis and statistical method: *(List the statistical test(s) planned and describe the strategy intended to evaluate the data).*

……
……

7. Animal model:

7.1 Description of animals

Common name	Genus and species	Strain	Age	Weight	Sex	Number
…….	……	……	…	…….	…	…….
…….	……	……	…	…….	…	…….

Special consideration: *(List specialized requirements for the research animals, if any)*-.....

7.2 Source/Vendor**:**

☐ Nature (*Perform without contravention to law and careful execution. Recognizing the health of animals, endangered species and ecosystems*)**.**

☐ Laboratory animals from .....
(*With genetic quality and health certificates*)

☐ Commercial source, please specify …….....……..

☐ Other, please specify …….....……..

7.3 Transportation…….

7.4 Prevention of injury and/or infection…….

7.5 Quarantine

☐ No

☐ Yes, please specify (Method, area and period)…….

……..

8. Scientific justification for animal species and number requested.

8.1 Animal model and species justification*: (Provide a scientific justification for the choice of animal model(s). What physiological and morphological characteristics does this animal possess that make it the best possible model?)*

…….

…….

8.2 Number of animals required: *(Provide an explanation of how the numbers of Animals to be used in each group or total were appropriate. Number of animals used in the experiment should be based on scientific and statistical requirements to achieve objectives).*

……..…….**.....**

…….

9. Animal care:

9.1 Study location: *(Study room where the animals will be housed.)*

……

9.2 Housing system:

☐ Open system

☐ Closed system

☐ Semi system

☐ Other, please specify ……...

(Sheltered, Outdoor, Naturalistic)

9.3 Macroenvironment (In room)

9.3.1 Temperature

☐ ……..….°C

☐ Ambient temperature

9.3.2 Humidity …….....….

9.3.3 Ventilation …….....……..

9.3.4 Illumination

9.3.4.1 Light source

☐ Natural ☐ Fluorescent/ LED …….....…. Lux

☐ Other, please specify …….….....……

Intensity …….....**.....**.... Lux

9.3.4.2 Photoperiod …….....……

9.3.5 Noise and vibration control

☐ No

☐ Yes, please describe …….....…….

9.4 Microenvironment (In water):

9.4.1 Water system

☐ Recirculation system

☐ Flow-through/single-pass system

☐ Static system

☐ Other, please specify ……...

9.4.2 Water quality treatment and control

☐ Water pre-treatment and chemical removal

[ ] No

[ ] Yes, please specify (chemicals/ozone/UV/etc). ……...……

☐ Water quality control

[ ] Parameters, please specify……..……

[ ] Frequency of water quality testing, please specify ……

[ ] Water changing schedule : ….....….... days;

Changing: …….....…. %

☐ Water temperature control

[ ] No

[ ] Yes, please specify……

9.4.3 Life support system

☐ No

☐ Yes, please specify

[ ] using life support system

[ ] Other, please specify ..…….....

9.4.4 Behavioral management

☐ No

☐ Yes, environmental enrichment will be provided to elicit appropriate behaviors

9.4.5 Social management

☐ Single housing because ….....……

☐ Social housing, number of animals per tank ….....…….....…

9.5 Sanitation (Method and material)

……..…….……

……..

9.6 Food:

Type of food: ☐ Commercial feed

☐ Other, please specify …….

Feeding schedule: ……

9.7 Aquatic animal tank

9.7.1 Size ……..…..…… Volume …….....……..…

9.7.2 Material …….....…….….

9.7.3 Stocking density (Number of animals per liter/ton) ….....**.....**

9.8 Substrate

☐ No

☐ Yes, please specify……

10. Health monitoring: *(Describe the criteria used for health evaluation while the animals are on Study.)*

…….

11. Animal welfare:

11.1 Replacement, Reduction and Refinement. (*Briefly describe how you have considered each of the following alternatives (the 3Rs) or why they are not applicable*

11.1.1 Replacement of animals *(e.g., with in vitro models, computer models or less sentient animals)*:

……..……. ……

…….

11.1.2 Reduction in the number of animals *(e.g., using appropriate statistical methods in the design and analysis of the study; reduction in experimental variability by using animals of defined genetic or microbiological status):*

…….

……..

11.1.3 Refinement of experimental procedures to minimize pain or distress *(e.g., early endpoints; use of analgesics, anesthetics or sedatives; techniques that reduce stress in the animal.):*

……..……..

……..…..

11.2 Anesthesia

☐ Yes ☐ No

If YES, please answer the following questions:

11.2.1 Route of administration

☐ Non-chemical methods, please describe…….

☐ Chemical methods

[ ] Inhalation

[ ] Parenteral

11.2.2 Anesthetic agent(s) used:

1) Name: ……..…….

2) Dosage: …….

3) Stage of anesthesia……

12. Surgery:

☐ Yes ☐ No

If YES, please answer the followings:

Surgical procedure is: ☐ Underwater ☐ Out of water surgery

Surgery techniques: ☐ Non-recirculating system

☐ Recirculating system

12.1 Location: *Give the location/room number for the proposed surgical procedure.*

…….

12.2 Surgeon/qualification*: Indicate who will perform the surgery, and his/her qualifications, training, or experience in the proposed procedure.*

……
……

12.3 Procedure: *Describe in detail the surgical procedure*. ……
……
……

12.4 Pre- and post-operative provision: *Detail the provision for both pre-and post-operative care, including provisions for post-surgical observation.*

……
……

12.5 Describe long-term care of chronic survival procedure.

……
……

13. Blood, body fluid withdrawal/tissue and organ collection.

Are the animal survived during blood/ body fluid collection?

	Method/Anatomic location	Needle size/ catheter size and length	Biopsy size	Volume collected (ml)	Frequency
Blood withdrawal	…….	…….	……	…….	…….
Body Fluid withdrawal	…….	…….	…….	…….	…….
Tissue collection	…….	…….	…….	…….	…….
Other please describe	…….	Please describe :			…….

14. Restraint with mechanical devices:

☐ Yes ☐ No

If YES, describe device, duration of restraint, frequency of observation, conditioning procedures and steps to assure comfort and well-being.

……
……

If prolonged restraint is used, must provide justification:

……
……

15. Project involving food and water deprivation, or dietary manipulation:

☐ Yes ☐ No

If YES, describe methods for assessing physical conditions, discomfort, stress, and distress during the course of study. Include clinical signs or manifestations expected.

……

	Amount restricted/added	Duration	Compound supplemented	Compound deleted	Frequency
Food restriction	…….	…….	…….	…….	……
Fluid restriction	…….	…….	…….	…….	……
Nutrient alterations	…….	…….	…….	…….	……

16. Tumor and disease models, toxicity testing:

☐ Yes ☐ No

If YES, describe methodology used for tumor/disease and/or toxicity testing. State objective criteria used to assess physical condition and pain, discomfort, stress, and distress during the course of study, including clinical signs or manifestations expected from the procedure. What criteria will be used to determine a humane endpoint before severe morbidity and death?

…….
…….

17. Behavioral studies:

☐ Yes ☐ No

If YES, describe in detail types of behavioral manipulations, including placement in testing chambers or apparatus, use of adverse stimuli, duration of test periods, and frequency of test periods.

…….
…….

18. Study endpoint: (State *the endpoint for the animals in this protocol. Indicate whether recovery, euthanasia, or death is/are expected, and when the animal experimentation phase will be stopped*

…….. ……..
……..

19. Euthanasia / Disposition of animals

19.1 Disposal of animals after completion of activity, the animals will be:

☐ Euthanized ☐ Returned to production/breeding unit/facility inventory

☐ Transferred to another research project:

– Protocol No. …… and investigator …….

☐ Other (Please describe) ……

19.2 Euthanasia method

☐ Chemical

- Substance and dose used for euthanasia …….....
- Route of administration …….....

☐ Mechanical, please specify …….....…….

☐ Other, please specify …….....…….

20. Necropsy/ Selected tissue and sample collection

☐ No

☐ Yes, please describe.

– Location.....

– Who will do it, and what is their experience in the technique used? ....

……

– Personnel protective equipment (PPE) .....

……

21. Animal tissue and carcasses disposal: *Describe method used to dispose animal tissue and carcasses.*

……

……

22. Biohazard/safety:

☐ Infectious agent (s) is/are used: specify ……

Please provide the certificate of biosafety approval

☐ Biohazardous chemical or carcinogen or radioactive material is/are used specify ……

☐ Recombination agent(s) is/are used: specify ……..…

☐ None

22.1. Provide a list of any potential biohazards associated with this proposal:

Specify Biosafety Level (1 or 2). Please see biosafety guidelines (page 107 – 174) to detail. (http://research.buu.ac.th/web2015/file/Guideline.pdf)

[ ] Biosafety level 1 ……..……

[ ] Biosafety level 2 …….....……..

22.2 Explain any safety precaution or program designed to protect personnel From biohazard and any surveillance procedure in place to monitor potential exposure.

…….……..

…….

22.3 Explain how the waste is decontaminated and disposed.

……

…….….

22.4 List primary safety equipment and personnel protective equipment requirements.

…….....

…….……

22.5 List procedures if any accident, injury or illness occurs.

……..

……

22.6 List specific treatment provision for accidental exposure.

…….

…….

22.7 List relevant occupational medical health provision**.**

……

……

23. Qualification of personnel:

List all individuals who will be involved in this protocol. If personnel do not have experience in working with animals, state how they will be trained

Name	Responsibilities	Description of relevant experience or training
……	……	……...
……	……	……...
……	……	……...
……	……	……...
……	……	……...
……	……	……...

As Principal investigator on this protocol, I verifies that the information herein is true and correct and that I am familiar with and will comply with standard of animal care and use established under the ethical guidelines and policies of Mahidol University, and Office of the National Research Council of Thailand (NRCT). Additionally, I acknowledge my responsibilities and provide assurances for the followings:

A. Animal use: The animals authorized for use in this protocol will be used only in the activities and in the manner described herein, unless a deviation is specifically approved by the MU-ACUC.

B. Duplication of effort: I have made a reasonable, good faith effort to ensure that this protocol is not an unneccessary duplication of previous experiments.

C. Statistical assurance: I assure that I have consulted with qualified statistician to evaluate the statistical design or strategy of this proposal, and that the minimum number of animals needed for scientific validity are used.

D. Biohazard/safety: I have taken into consideration, and I have made the proper coordinations regarding all applicable rules and regulations concerning radiation protection, biosafety, recombinant issues, etc., in the preparation of this protocol.

E. Training: I verify that the personnel performing the animal procedures/manipulations described in this protocol are technically competent and have been properly trained to ensure that no unneccessary pain or distress will be caused as a result of the procedures/manipulations.

F. Responsibility: I acknowledge the inherent moral and administrative obligations associated with the performance of this animal use protocol, and I assure that all individuals associated with this project will demonstrate a concern for the health, comfort, welfare, and well-being of the research animals. Additionally, I pledge to conduct this study in the responsibility for implementing animal use alternatives where feasible, and conducting humane and lawful research.

G. Scientific review: This proposed animal use protocol has received appropriate peer scientific review, and is consistent with good scientific research practice.

H. Research studies: This protocol **IS** or **IS NOT** (circle one) associated with a grant application. If yes, I certify that this protocol is essentially the same as the study found in the grant application or program/project. The MU-ACUC and the funding agency will be notified of any changes in the proposed project, or personnel, relative to this application. I will not proceed with animal experiment until approval by the MU-ACUC is granted.

…… ……

(Principal investigator) Date