Animal Care and Use Protocol
Traditional Laboratory Animals Study Protocol

(กรอกข้อมูลเป็นภาษาไทย หรือ ภาษาอังกฤษ)

Protocol number		This section will be filled by the BUU-IACUC
Date of submission (dd/mm/yyyy)		
Date of approval or request revision (dd/mm/yyyy)		
Date of resubmission (dd/mm/yyyy)		
Date of approval or disapproval (dd/mm/yyyy)		
Date of expiration (dd/mm/yyyy)		

1. Protocol title:

(Thai) .....

(English) .....

If this protocol is a part of the main project, please provide the main project title

(Thai) .....

(English) .....

Principal investigator of the main project

Name ..... Affiliation .....

Phone..... E-mail.....

Animal use license no ..... Expired date .....

Principal investigator of the main project

Name ..... Affiliation.....

Phone ..... E-mail.....

Animal use license no ..... Expired date .....

2. Principal investigator of the submitted protocol: *For a student thesis, the principal investigator is the principal adviser and the student is a co-investigator*.

Name ..... Affiliation.....

Phone ..... E-mail.....

Animal use license no ..... Expired date .....

3. Co-Investigators:

3.1 Name..... Affiliation.....
Phone ..... E-mail.....
Animal use license no ..... Expired date .....
3.2 Name..... Affiliation.....
Phone ..... E-mail.....
Animal use license no ..... Expired date .....
3.3 Name..... Affiliation.....
Phone ..... E-mail.....
Animal use license no ..... Expired date .....

4. Contact person in case of emergency

Name..... Affiliation.....
Phone ..... E-mail.....

5. Type of animal protocol:

☐ Research: in the field of .....
☐ Testing/Monitoring, specify .....
☐ Teaching: course title/ level.....
☐ Biological production, specify .....
☐ Animal breeding, specify.....
☐ Other, specify.....

6. **Anticipated protocol period:** From ……..... to .....
(วันเริ่มต้นต้องไม่ก่อนวันที่โครงการได้รับการรับรอง)

7. Grant proposal: Please select **ONE** of the following options

☐ To be submitted; from.....
Amount requested .....
Funding period from .....to .....
☐ Has been submitted; from.....
Amount requested .....
Funding period from .....to .....
☐ Received from.....
Amount requested .....
Funding period from .....to .....
☐ Other.....

Your signature(s) as Principal investigator (PI) and Co-investigator(s) on this application verify that the information herein is true and correct and that you are familiar with and will comply

with the standard of animal care and use established under the ethical guidelines and policies of Burapha University (BUU) and Office of the National Research Council of Thailand (NRCT).

Principal investigator: Name …….....……

_____ _____
(Signature) (Date)

Co-investigator: Name …….....……

_____ _____
(Signature) (Date)

Co-investigator: Name …….....……

_____ _____
(Signature) (Date)

Co-investigator: Name …….....……

_____ _____
(Signature) (Date)

****

Approval:
BUU-IACUC review: ☐ Approved ☐ Disapproved

_____ _____
(Chair, BUU-IACUC) (Date)

Burapha University
Standardized Research Protocol Format
for Permission of Animal Care and Use

1. Protocol title:

(Thai) ....

(English) ..... .

2. Non-technical summary: *Provide a brief description of the project that is easily understood by non-scientists, expressing its significance and your reasons for undertaken the study.*

.....

.....

3. 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.*

.....

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

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5. Potential benefits of the study: *Explain how the study is important to human or animal health and the advancement of knowledge.*

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6. Experimental design and general procedures: *Provide a complete description of animal use, including animal species, study groups, and what will be done to the animals. Succinctly outline the formal scientific plan and direction for experimentation. A diagram or chart may be helpful to explain complex design.*

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7. Animal used and justification:

7.1 Description of animals

Common name	Genus and Species	Strain/Stock	Age	Weight	Sex	Number
Rat	*Rattus norvegicus*	Wistar Example	8 wk	280-300g	Male	30

7.1.1 Special consideration: *List specialized requirements for the research animals,*

e.g. certain antibody or virus free, Pasteurella free, etc

…….....

7.1.2 Source/ Vendor: .....

7.1.3 Transportation**:** .....

…….....

7.2 Scientific justification for animal species; number requested; and data analysis.

7.2.1 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?*

.....

.....

7.2.2 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.*

.....

.....

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

.....

.....

8. Animal care: *Provide all husbandry consideration.*

8.1 Study location: *Study room where the animals will be housed.*

…….....

…….....

8.2 Housing System:

☐ Conventional

☐ Strict hygienic conventional

☐ Other, specify.....

8.3 Caging:

☐ Mouse
- ☐ Plastic cage (size 10 x 13 x 5 inches)
- ☐ Individual ventilated cage (IVC)
- ☐ Metabolic cage
- ☐ Other, specify.....

☐ Rat
- ☐ Plastic cage (size 10 x 18.5 x 6 inches)
- ☐ Individual ventilated cage (IVC)]
- ☐ Metabolic cage (BW≤300 g)
- ☐ Other, specify.....

☐ Other, specify.....
……

8.4 Social housing condition:

☐ Yes, specify number of animal per cage……
☐ No, provide scientific justification for not socially housing the animals
.....

8.5 Environmental requirements:

Temperature .....
Humidity.....
Light ☐ Standard fluorescent
☐ Other, specify.....
Light cycle ☐ Standard (12:12 hrs.)
☐ Other, specify.....

8.6 Food:

Type of food ☐ Standard diet
☐ Other, specify.....
Feeding schedule ☐ Ad libitum
☐ Other, specify.....

8.7 Water:

Type of water ☐ Filter water
☐ RO water contains 2-3 ppm chlorine
☐ Other, specify.....
Provision of water ☐ Ad libitum
☐ Other, specify.....

8.8 Bedding:

Type of bedding ☐ Autoclaved corn cob .....
☐ Other, please specify.....
Schedule of bedding changing:
☐ Weekly
☐ At specified interval, every……day(s)

9. Veterinary medical care: *Describe the routine veterinary care. List the criteria used for health evaluation while the animals are on study.*

.....

.....

10. Animal welfare:

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

10.1.1 Database(s) searched……..…….

10.1.2 Date of search: *must be within six months prior to IACUC meeting dd/mm/yyyy*

.....

10.1.3 Period of information searched: *range of years searched*

.....

10.1.4 Keywords used in search .....

.....

10.1.5 Results of search*: provide a narrative description of the results of the literature search.*

☐ No .....

☐ Yes, explain why it is scientifically necessary to duplicate any previous work?

.....

.....

10.2 Briefly describe how you have considered each of the following alternatives (the 3Rs) or why they are not applicable.

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

.....

.....

10.2.2 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; sharing tissue among investigators.*

.....

.....

10.2.3 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.*

.....

.....

10.3 Potential animal pain and distress assessment:

Are the animals expected to experience any specific study-induced or related Problems *i.e. health problems, pain, distress, complications, etc.* or any health problems as a result of the phenotype of the animal?

☐ No ☐ Yes

If yes, please answer the following questions

10.3.1 Describe the expected problems

.....

.....

10.3.2 What criteria will be used to assess pain, distress, or Discomfort?
Check all that apply

☐ Inactivity
☐ Loss of appetite
☐ Loss of weight
☐ 5% ☐ 10 % ☐ 15% ☐ 20% weight loss
☐ Restlessness
☐ Abnormal resting postures, somnolence or hunched posture
☐ Licking, biting, scratching, or shaking a particular area
☐ Failure to show normal patterns of inquisitiveness
☐ Failure to groom, causing and unkempt appearance
☐ Guarding (protecting the painful area)
☐ Loss of mobility
☐ Red stain around the eyes of rats
☐ Unresponsiveness
☐ Self-mutilation

☐ Labored breathing
☐ Tumor burden
☐ Other (please list) .....

10.3.3 How often will the animals be monitored for these signs of pain and distress?

.....

10.3.4 Who will monitor the animals?

.....

10.4 Anesthesia:

☐ No ☐ Yes

If yes, please answer the following questions

1) Preanesthetic preparation: ....
2) Type of anesthesia used, if applicable: .....
3) Dose: .....
4) Route of administration: .....
5) Frequency of anesthesia: .....
6) Length of anesthesia: .....
7) What criteria will be used to assess level of anesthesia?
Check all that apply

☐ Respiration rate ☐ Heart rate
☐ ECG ☐ Toe pinch
☐ Tail pinch ☐ Corneal reflex
☐ Color of mucous membrane ☐ Muscular relaxation
☐ Other (pulse oximeter, respirometer) please list……..

8) Who is responsible for maintaining anesthesia?.....
.....

9) Methods used to monitor anesthesia, frequency of monitoring
.....
.....

10) If inhalation anesthetics are used, describe the system for scavenging waste anesthetics gas.
.....
.....

11) How animals are kept warm?
.....
.....

12) Describe post-anesthetic treatment or intervention: .....
.....
.....

11. Surgery:

☐ No ☐ Yes

If yes, please answer the following

11.1 Surgical procedure is

☐ Non-survival ☐ Survival
☐ Major ☐ Minor
☐ one time ☐ Multiple

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

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

11.4 Surgical procedure: *Describe in detail any surgical procedures planned and/ or add a reference.*
.....
.....

11.5 Pre- and Post-operative provisions: *Detail the provisions for both pre-and post-operative care, including frequency of monitoring, supportive care, analgesia, and wound care.*
.....
.....

11.6 Describe long-term care of any chronic survival procedures: .....
.....

11.7 Multiple survival surgery procedures: *Multiple major operative procedures on the same animal must be adequately justified for scientific reasons by the principal investigator in writing.*

11.7.1 Procedures: .....

.....

11.7.2 Scientific Justification: .....

……

11.8 Who will be responsible for post-surgical care and treatment?

.....

.....

12. Blood or Body Fluid Withdrawal/ Tissue Collection/ Injections, Tail Clip, Gavage:

Describe in detail the method(s), needle sizes, volume(s) collected or administered, and frequency of collection or injections.

	Method/ Anatomic Location	Needle size/ Catheter Size and length	Biopsy Size	Volume Collected (ml)	Volume Administered (ml)	Frequency
Blood withdrawal						
Body fluid withdrawal						
Tissue Collection						
Injection/ Infusion						
Tail Clip/ Puncture						
Gavage						
Other						

13. Drugs/Chemicals used: *Describe the experimental drugs/chemicals, dose, route of administration, frequency-duration, and the purpose of use.*

Drugs/Chemicals	Dose (mg/kg body weight)	Route of administration/ chemical	Frequency & duration	Purpose

13.1 Drug/chemical grade:

☐ Pharmaceutical grade

☐ Non-pharmaceutical grade, specify .....

13.2 Post-administration monitoring:

.....

.....

13.3 The criteria used to determine if an animal is in pain, distress, or discomfort:

e.g.: loss of mobility, failure to groom, abnormal posture, licking/biting wound area.

.....

.....

13.4 Post-administration care:

.....

.....

14. Restraint with mechanical devices:

☐ No ☐ Yes

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. Food and water deprivation, or dietary manipulation:

15.1 Does this protocol involves food and water deprivation, or dietary manipulation?

☐ No ☐ Yes

If **yes**, describe methods for assessing conditions, pain, discomfort, stress, and distress during the course of study. Include clinical signs and symptoms expected.

.....

.....

15.2 Provide detail of these procedures in Table below

	Amount restricted/ added	Duration	Compound supplemented	Compound deleted	Frequency
Food restriction					
Nutrient alterations					
Other					

16. Tumor and disease models, toxicity testing:

☐ No ☐ Yes

If **yes**, describe methods for assessing physical conditions, 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:

☐ No ☐ Yes

If **yes**, describe types of behavioral manipulations, including placement in testing chambers or apparatus, use of aversive stimuli, duration of test periods, and frequency of test periods.

.....

.....

18. Endpoints: *Specific humane endpoints must be clearly defined in all animal protocols.*

18.1 Study/ experimental endpoint: *Describe the endpoint for the animals in this protocol when the scientific aims and objectives have been reached.*

.....

.....

18.2 Humane (Early) endpoint is used: *The animals are humanely euthanized prior to the expected date of study termination.*

☐ No

☐ Yes

If **yes**, please specify early endpoint **criteria** used are .....

.....

18.3 Death or moribund as an endpoint is used:

☐ No

☐ Yes, answer the following

18.3.1 Criteria that establish when the endpoint has been reached, and describe how animals will be monitored and care for

.....

.....

18.3.2 Identification of personnel responsible for evaluating animal condition, record keeping, and notification of the investigator and/or veterinarian to perform euthanasia.

.....

.....

19. Euthanasia/ Disposition of animals:

19.1 Disposal of animals after completion of activity:

☐ Euthanized

☐ Return to production/breeding unit/facility inventory

☐ Transfer to another research project:

– please list protocol and investigator .....

☐ Other (Please describe) .....

19.2 Euthanasia method:

☐ CO_2-compressed carbon dioxide gas in cylinders

☐ Anesthetic/Sedative(s)

Agent(s) .....

Dosage .....

Route of administration .....

☐ Cervical dislocation
☐ performed with anesthesia
☐ performed with no anesthesia, provide scientific justification .....
☐ Decapitation, provide scientific justification .....
☐ Other (Please describe) .....

20. Necropsy/ Selected tissue and sample collection:

☐ No
☐ Yes, please describe.

– Location (สถานที่ทำการผ่าซาก/เก็บตัวอย่าง) .....
– Who will do it, and what is their experience in the technique used?
.....
– Personnel protective equipment (PPE) .....
.....

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

.....
.....

22. Occupational health and safety:

22.1 Type of hazards associated with this protocol.

☐ None
☐ Hazardous chemical(s), carcinogen(s) or radioactive material(s) is (are) used: specify
.....
☐ Biohazardous agent is (are) used
☐ Non-Infectious agent: specify .....
☐ Infectious agent: specify .....

22.2 Specify Biosafety Level

Level (1, 2 or 3). Please see biosafety guidelines (page 107 – 174) to detail. (http://research.buu.ac.th/web2015/file/Guideline.pdf)

.....
.....

22.3 Explain any safety precautions and protective measures to protect personnel from biohazards and any surveillance procedures in place to monitor any potential exposures.

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.....

22.4 Explain how the waste is decontaminated and disposed.

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.....

22.5 In case of accidental, provide immediate procedures and early treatment to limit possible injury or illness.

.....

.....

22.6 List relevant occupational medical health provision.

.....

.....

23. Qualifications of Personnel: *List all individuals who will be involved in this protocol. If personnel do not have experience, state how they will be trained.*

Name/Status	Qualification/Recent trainings in the use and care of laboratory animals	Responsibilities in the project

24. List of References used in writing protocol.

.....

.....

25. Assurances: As the PI on this protocol, I verify 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 Burapha University; Office of the National Research Council of Thailand (NRCT) and Animal for Scientific Purposes Act B.E.2558 (2015). Additionally, I acknowledge my responsibilities and provide assurances for the followings:

25.1 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 modification is specifically approved by the BUU-IACUC prior to its implementation.

25.2 Duplication of effort: I have made every effort to ensure that this protocol is not an unnecessary duplication of previous experiments.

25.3 Statistical assurance: I assure that I have consulted with a qualified individual who evaluated the experimental design with respect to the statistical analysis, and that the minimum number of animals needed for scientific validity will be used.

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

25.5 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 unnecessary pain or distress will be caused to the animals as a result of the procedures/manipulations.

25.6 Responsibility: I acknowledge the inherent moral, ethical 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.

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

25.8 Painful procedures: A signature for this assurance is required by the Principal Investigator if the research being conducted has the potential to cause more than momentary or slight pain or distress even if an anesthetic or analgesic is used to relieve the pain and/or distress. I am not conducting biomedical experiments, which may potentially cause more than momentary or slight pain or distress to animals.

25.9 Research studies: The BUU-IACUC 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 BUU-IACUC is granted.

Signature …….....……

(Principal investigator)

Date …….....……..……..