The City College of NY

Institutional Animal Care & Use Committee

Instruction for submission of a research protocol to the

Institutional Animal Care and Use Committee (IACUC)

Instructions:

1. A separate form is required for each species.
2. The protocol submission form must be typed *within* the body of the form.
3. Typed name and signature of the PI on page 1 is required for every protocol to be reviewed.
4. SUBMIT NO OTHER FORMS or DOCUMENTS. NO ATTACHMENTS ARE ALLOWED.
5. Submit the signed original to Mr. Harry Acosta Marshak Vivarium.
6. Email the protocol to: iacuc@ccny.cuny.edu

Notes:

1. Only a completed and appropriately signed form will be approved.
2. Most items are self-explanatory.
3. **Projects are approved for three years, with an annual continuing review required.
Without the annual review, the project is terminated.
Indicate the number of animals to be used for the research or teaching project, not per year.**
4. Justify the number of animals needed. The numbers of animals are approved for the project, not per year.
5. All animals shall be ordered by the Animal Care Facility not by the investigator.
6. All changes to the approved protocol must be discussed with the attending Veterinarian prior to implementation. Significant changes require an amendment. Even minor changes require approval.
7. Each person with significant animal contact must have Employee Health Program Clearance.

Use Shade or **Bold** to indicate changes in text of resubmitted materials.

**Do not submit copies of this instructional page.**

# Call 650-8515 or fax 650-7545 if you need assistance

## Preferred Anesthesia, analgesia, and euthanasia in commonly used laboratory animal species.

## \*Pentobarbital is difficult to obtain in the U.S. and, in many cases, is cost-prohibitive. Researchers are encouraged to use alternative drugs, e.g., ketamine-xylazine.

## Small Animals

|  |  |  |
| --- | --- | --- |
| Mice | General Anesthetics | Inhalants – Isoflurane in bell jar (use hood) for short procedures (bleeding etc.)Isoflurane 1.5 – 2.5% to maintain surgical anestheticInjectables: -Pentobarbital 40-60 mg/kg IP- Ketamine 1 mL of 100 mg/mL + xylazine 0.5 mL of 20 mg/mL + saline 8.5 mL: administer 0.1 mL/30 gm body weight IP Dose Ketamine 100 mg/kg + xylazine 10 mg/kg- Avertin (tribromoethanol) 250 mg/kg IP (0.2 ml/10 g, 1.2% sol) must be stored away from light to avoid decomposition |
| Analgesics | Buprenorphine 0.1 – 0.5 mg/kg SQ, IP every 6-8 hours |
| Sedation | 70% CO2 / 30% O2 to effectKetamine 44 mg/kg + acetylpromazine 0.75 mg/kg IP |
| Euthanasia | 100% CO2 to effect. *Note: neonates are resistant to CO2 and require longer exposure. The chamber cannot be pre-charged prior to animal placement.* |
| Rats | General Anesthetics | Inhalants – Isoflurane in bell jar (use hood) for short procedures (bleeding etc.)Isoflurane 1.5 – 2.5% to maintain surgical anestheticInjectables: - Pentobarbital**\***  40-60 mg/kg IP - Ketamine 50 – 70 mg/kg with xylazine 5-7 mg/kg IP |
| Analgesics | Buprenorphine 0.05 mg/kg SQ for every 8-12 hours |
| Sedation | 70% CO2 / 30% O2 to effect |
| Euthanasia | 100% CO2 to effect, Pentobarbital 100 mg/kg IP or IV |
| Rabbits | General Anesthetics | Inhalants: - Isoflurane 1.5 – 2.5% to maintain surgical anestheticInjectables- Ketamine 35 mg/kg with xylazine 5 mg/kg IM. Incremental doses of 1/3 of the original ketamine-xylazine dose may be used to prolong anesthesia. |
| Analgesics | Buprenorphine 0.03 – 0.05 mg/kg SQ every 6-12 hours |
| Sedation | Ketamine and acepromazine missed 1:1 v/v. Give 0.1 mL/kg IV Acepromazine 0.25 mg/kg IM. |
| Euthanasia | Pentobarbital100 mg/kg IV |
| Guinea Pigs | General Anesthetics | Inhalants: Isoflurane/ O2 via masks 1.5 – 2.5% to maintain surgical anestheticInjectablesKetamine 40 – 100 mg/kg with xylazine 4 – 13 mg/kg IMPentobarbital 15 – 40 mg/kg IP |
| Analgesics | Buprenorphine 0.2 – 0.8 mg/kg SQ, IM every 6-12 hours |
| Sedation | 70% CO2 / 30% O2 to effectDiazepam or midazolam 1 – 5 mg/kg IM, IPTelazol 10 – 80 mg/kg IM, IP |
| Euthanasia | 100% CO2  to effect, Pentobarbital100 mg/kg IV |

##

##

##### PAIN OR DISTRESS CLASSIFICATION

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Classification:** |  |  | **B** |  | **C** |  | **D** |  | **E** |

##### **Classification B: Animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery, but not yet used for such purposes. *Examples:***

##### Breeding colonies of animal species that are held in legal sized caging and handled in accordance with the Guide and other applicable regulations. Breeding colony includes parents and offspring.

##### Newly acquired animals that are held in proper caging and handled in accordance with applicable regulations.

* Animals held under proper captive conditions or wild animals that are being observed.

##### **Classification C: Animals upon which teaching, research, experiments, or tests will be conducted involving no pain, distress, or use of pain-relieving drugs.**

##### ***Examples:***

##### Procedures performed correctly by trained personnel such as the administration of electrolytes/fluids, administration of oral medication, blood collection from a common peripheral vein per standard veterinary practice or catheterization of same, standard radiography, parenteral injections of non-irritating substances. (Injections, blood sampling, tube feeding, behavioral studies w/o restraint, blood pressure measurement, anesthesia without recovery for immediate organ removal, and/or minor surgical procedures under local anesthesia e.g. biopsies, catheterization.

* Euthanasia performed in accordance with the recommendations of the 2000 AVMA Panel on Euthanasia, utilizing procedures that produce rapid unconsciousness and subsequent humane death.

##### **Classification D: Animals upon which experiments, teaching, research, surgery, or tests will be conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs will be used.**

##### ***Examples:***

##### Major or multiple surgery conducted under anesthesia or prolonged non-survival surgical

##### Administration of drugs, chemicals, toxins, or organisms that would be expected to produce pain or distress but which will be alleviated by analgesics. (Freund’s adjuvant for immunization, ascites production, tumor production, etc.)

* Prolonged periods of physical restraint, induction of behavioral stress, induction of aggressive behavior producing self-mutilation, alteration of perceptual or motor functioning, application of noxious stimuli from which escape is impossible.
* Blood collection by more invasive routes such as intracardiac or periorbital collection under anesthesia.
* Minor surgical procedures conducted by trained personnel in accordance with standard veterinary practice such as biopsies, gonadectomy, exposure of blood vessels, chronic catheter implantation and laparoscopy performed under anesthesia.

##### **Classification E: Animals upon which experiments, teaching, research, surgery, or tests will be conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs will adversely affect the procedures, results, or interpretation of the research, teaching, experiments, surgery, or tests.**

***Examples:***

##### Procedures producing pain or distress unrelieved by analgesics such as toxicity studies, microbial virulence testing, radiation sickness, and research on stress, shock, or pain. (Burn or severe trauma infliction on anesthetized animals with subsequent recovery, inducing psychotic-like behavior such as inescapable or terminal stress, use of muscle relaxants, paralytic for surgical restraint w/o anesthesia).

##### Surgical and post-surgical sequellae from invasion of body cavities, orthopedic procedures, dentistry or other hard or soft tissue damage that produces unrelieved pain or distress.

* Negative conditioning via electric shocks that would cause pain in humans.

Use a Separate Form for Each Species FOR IACUC USE ONLY

|  |
| --- |
| Protocol Number       FULL Review Initial SubmissionReview Date      Approval Date       |

This form must be typed and filled-in

completely, and, signed by investigator

prior to Review.

Call 650-8515 or fax 650-7545 for assistance

The City College of NY

Institutional Animal Care & Use Committee

IACUC PROTOCOL APPLICATION SUMMARY FORM

FOR THE USE OF LIVE VERTEBRATES FOR RESEARCH OR TEACHING

Section A – Investigator and Animal Use Information

|  |  |  |  |
| --- | --- | --- | --- |
| Principal Investigator:     E-mail Address:      | Department:      | Mailing Address:     Phone:      | Category for Pain and Distress: (required)[ ]  B [ ]  D[ ]  C [ ]  E |
| PROJECT TITLE  |

Funding

Are you applying for, or receiving funds for the proposed experiments from external or internal sources that requires peer review? Yes [ ]  No [ ]

If YES, identify the funding agency (ies) by name and I.D. # below (e.g., NHLBI, L12345):

|  |
| --- |
| Agencies and numbers:     If relevant, your NIH assignment number must be provided.  |
| Species common name:      | Number of approved animals for this 3 year project:      | Number of animals for year 1:      |

|  |
| --- |
| Investigator Assurance: I will follow the ILAR Guide for the Care and Use of Laboratory Animals and the Animal Welfare Act Regulations administered by the United States Department of Agriculture. I understand that these laws and regulations are applicable to all biomedical research projects using animals that are funded through and administered by City College. As required by the Animal Welfare Act regulations, I hereby assure the IACUC that this experiment does not unnecessarily duplicate previous experiments. Furthermore,I will obtain the approval of the IACUC for any significant changes in the experiment before they are implemented. I certify that the statements herein are true, complete and accurate to the best of my knowledge. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. I accept responsibility for the scientific conduct of the project. I also certify that the experiments described in this protocol faithfully reflect the work proposed in the sponsored project(s) identified on page one of this application. (“Per” signatures not acceptable)  Signature: Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_Typed faculty rank and/or title of PI:      Date       |

Location, Drug Use and Hazards

1. HOUSING of Animals upon Arrival:

|  |  |
| --- | --- |
| Housing Location | Maximum number to be housed at one time |
| Mice: Barrier: |       |
| Quarantine: |  |
| Rat:      |       |
| Other:      |       |

2. SATELLITE: If the animals are to be kept away from the Central Facilities for longer than 24 hours, provide the following information:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Building      | **Room #**      | **Length of time at this location**      | **# to be housed**      | **Responsible Individual**      |

3. PROCEDURES and LOCATIONS WHERE WORK IS DONE: (Complete all that apply)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Procedure | Building | Room # | Length of time at this location | Responsible Individual |
| *In vivo* experiment (other than surgical procedures) |       |       |       |       |
| Immediate euthanasia (e.g., tissue/organ collection) |       |       |       |       |
| Non-survival surgery (animals euthanized at the end of the procedure) |       |       |       |       |
| Survival surgery (animals will away from anesthesia) |       |       |       |       |
| Post-operative care |       |       |       |       |

4. LIST DRUGS AND SUBSTANCES other than standard diet and emergency drugs to be used (i.e., injected, ingested or topically applied) in live animals:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| N/A | Drugs | Dosage | Route | Responsible Individual |
|  | Anesthesia: |       |        |       |
|  | Analgesic |       |       |       |
|  | Euthanasia |       |       |       |
|  | Protocol Specific Drugs |       |       |       |

Will non-pharmaceutical grade medication or experimental compounds be used in the protocol activity?

NO [ ]  YES [ ]

If yes, please justify and provide relevant information to the sterility, compatibility and purity of the chemical as well as the source.

5. HAZARDS: Indicate if the following hazards are used in the procedures done on live animals:

|  |  |  |  |
| --- | --- | --- | --- |
| Hazard \* | No | Yes | Location where the hazard will be used |
| Recombinant DNA | [ ]  | [ ]  |       |
| \*\* Infectious Agents | [ ]  | [ ]  |       |
| Toxic/Carcinogenic Materials | [ ]  | [ ]  |       |
| Radioisotopes | [ ]  | [ ]  |       |
| Irradiator (cesium source) | [ ]  | [ ]  |       |
| X-Ray, Fluoroscope | [ ]  | [ ]  |       |
| Non-Ionizing Radiation (laser, microwave, etc.) | [ ]  | [ ]  |       |

\* *Contact the Biosafety Committee or Radiation Safety Committee for approvals and provide authorizations as appropriate.*

\*\* All Cell Lines are considered potentially infectious.

* Contamination of biological specimens such as rodent cell lines, stem cells with rodent pathogens can result in devastating outbreaks of disease in animals implanted with these materials.
	+ Please submit a sample to IDEXX for IMPACT testing (Mice-Impact SC and Rats-IMPACT VI*)*
* Contamination of human cell lines, stem cells and tumors with human pathogens can pose the risk to research and Animal Care personnel.
	+ Please submit a representative sample to IDEXX for *h-Impact testing:*

 <http://www.idexxbioresearch.com/radil/Biological_Materials/IMPACT_-_The_MAP_Alternative/index.html>

**HAZARD INFORMATION:**

**Complete the information below for each substance to be used.**

The Investigator is responsible to contact Environmental Health & Safety to discuss hazard management and if an IRB review is required**.**

**Name of Agent:**

*List all drugs (include generic name), chemicals, or biological agents to be administered to animals.*

**Route of administration:**

**Indicate the dosage per kg., frequency, and duration of administration:**

**State the mechanism of secretion (urine, feces, breath, etc.):**

*Indicate if there is an active drug and/or active metabolite in excretions.*

*State whether active drugs or metabolites in excretions are volatile.*

*Indicate for how long the substance itself or metabolites are excreted*.

**Describe management of animal contact items (cages, bottles, etc.):**

**Describe management of animal carcasses:**

Describe the technical experience you and/or your staff have had with this specific material(s):

Section B – Protocol Summary

*No Attachments will be accepted unless specifically requested by this committee.*

Complete the Form (Sections A and B, Print it out and obtain appropriate signatures on page one (1). (All parts must be answered prior to review).

|  |
| --- |
| 1. A. Describe in *non-technical* terms the objectives of the work to be done on animals. Briefly explain the relevance this work will have to human or animal health, the advancement of knowledge or the good of society. Define all abbreviations.      |
| 1. B. If this is a 4th year renewal application, describe in *non-technical* terms what was learned during the last year and explain how the results influenced the continuation of the project. Include how many animals were used in those experiments. Define all abbreviations.Renewal? No[ ]  Yes[ ]  Progress ReportNumber of animals approved for the previous 3 year protocol:      Number of animals used to date:      Progress report, indicate findings, publications and justifications for continuing this protocol:      |
| 2. Literature Search: Are there alternatives to live animals? Yes [ ]  No [ ] Are there alternative to painful procedures? Yes [ ]  No [ ] Federal Regulations require that “the principal investigator has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals (**Category D or E**) and has provided a written narrative of the methods used to determine whether or not: o Suitable alternatives to the use of live animals are available o Alternatives exist to the painful procedures We believe that the performance of a database search remains the most effective and efficient method for demonstrating compliance with the requirement to consider alternatives to painful/distressful procedures. However, in some circumstances conferences, colloquia , subject expert consults or other sources may provide relevant and up-to-date information regarding alternatives, in lieu of, or in addition to , a database search. When other sources are the primary means of considering alternatives, sufficient documentation should be provided to the IACUC to demonstrate the expert’s knowledge of the availability of alternatives in the specific field of study.The narrative should include:* Two databases or other sources that must be consulted [such as, Medlin/PubMed, and Altweb or Agricola are preferred.
* Date of the search:
* Years covered by the search:
* Key words and/or search strategy: with number of citations used:

|  |  |  |  |
| --- | --- | --- | --- |
|  |  |  |  |
| Database Search | Date of Search | Years Searched | Search terms used | **Number of hits**  |
|

|  |  |  |
| --- | --- | --- |
| *e.g. Medline*  |  |  |

 |

|  |  |
| --- | --- |
| *April 15, 2013*  |  |

 | *1950 - present* | *Hypoxia + non-animal model* | *153* |
|  |  |  |  |  |

Enter description of the literature search here:      For any additional information, including direct contact with colleagues or other sources please enter the narrative here:       |
| 3. Why was this particular species chosen?       |
| 4. Describe the entire experimental design including hypotheses and specific aims of the study in the sections below.a. Statement of the hypothesis (if none – state the reason for animal use: for example, “training”):     b. Statement of all specific aims:     c. Details of animal use: (From day of animal arrival to completion/euthanasia)1. housing and any special husbandry requirements
2. experimental surgery/procedures/non-surgical procedures(specific details of surgery should be in section 9a)
3. applicable postoperative care and post-procedural monitoring
4. potential health complication
5. experimental end-point/euthanasia

  |
| 1. Describe the *known or expected* adverse effects of the planned procedures on the animal.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Tumor Size | Weight loss % | Inability to drink/eat | Behavioral signs | Applicable clinical signs | Other |
|  |  |  |  |  |  |

Include details/specific plan of the monitoring that will be used to evaluate the health of the animals and the procedures to be followed in case of adverse effects. e.g. *Animals will be monitored daily after the tumor injection. We will look for signs of infection at site and any signs the animals are in distress such as absence of grooming, weight loss, lack of feces in cage or scratching/biting at injection site. If needed, we will consult with ACF Veterinarian and humanely sacrifice with CO2.*       **5a. Genetically engineered animal use. Are there any changes in the animal genome that may result in any adverse effects on the animal?**  **Yes**[ ]  **No**[ ]  **N/A**[ ] If Yes, please describe:       |
| 6. If at the conclusion of your experiment animals are euthanized, describe in detail the method of euthanasia. Include the name and qualifications of the individual responsible for doing the procedure.      Secondary method of confirming death       |
| **7. Will the proposed research require the use of physical restraint of awake animals?**  Yes[ ]  No[ ]  If yes, please provide scientific justification and describe in details (including training of animals to adapt to restraint, observation intervals and veterinary care if adverse effects may occur),      7a. **Will any animals be subjected to fluid/food restrictions? (Not including NPO of pre-op animals)**   **Yes** [ ]  **No** [ ] If yes, please provide scientific justification and describe in details (including monitoring to ensure that nutritional needs are met; body weight monitoring periods, maintenance of written record)      |
| 1. If experiments include blood collection provide the method used to draw blood, frequency of bleeds and amount of blood drawn at any one time. If animals are anesthetized or sedated for blood drawings, specify what agent, dose and route of administration.

Yes [ ]  No [ ]  If yes, please provide details.       |
| 9. Does the experiment involve surgery (survival or non-survival) on live animals?Yes [ ]  No [ ]  If yes, answer the following questions: |
| 1. Describe the surgical procedure including:

 How will the animal, surgeon and instruments be prepared for aseptic surgery?  What is the duration of surgical procedure?  What will be used for pre-anesthetic/anesthetic agents and at what dosage and route of administration?       |
|  b. How will depth of anesthesia be monitored, how often, and who will do the monitoring?      |
|  c. Describe the use of post-surgical analgesics (agent, dose and route).       If protocol includes painful procedures for which analgesics must be withheld, provide scientific justification  **Describe your full postoperative/post anesthesia care.** Monitoring plan should include:  Immediate care and observation of the animal until it recovers.  Who will observe the animal during the recovery?  Note observation intervals during the entire postoperative period.  If skin sutures or clips are used, when will they be removed?  |
|  d. Will *multiple survival surgeries* be done on animals?No [ ]  Yes [ ]  If yes, provide scientific justification for requiring more than one survival procedure on the same animal :       |
|  e. Will neuromuscular blocking agents be used?No [ ]  Yes [ ]  If so, describe how the depth of anesthesia will be monitored:      |
| 10. PHS Policy requires a scientific justification for using the ascites method to produce antibodies:;Is the ascites method used? [ ]  No [ ]  YesIf yes, provide justification:        |
| Alternative methods you have considered that would avoid or minimize distress, discomfort and pain (including *in vitro* methods) and your reasons for concluding that those methods are unsuitable.      |
| **11**. **The number of animals requested for this protocol is based on the following** **(Select all that apply and explain below):** [ ] **A statistical estimation of the number of animals appropriate to the study design that justifies the number required to achieve statistical significance (i.e. group table, power/sample size analysis, etc.)** [ ] **The estimated minimum number necessary to achieve meaningful pilot study data** [ ] **The number necessary to obtain sufficient tissue and other material for testing or analysis**  [ ] The number required to provide sufficient technical training Provide details here:       |
| 12. If animals are transported to any location outside the Central Animal Facilities, give the location and describe the method and route of transport.      |
| 13. Persons to be contacted in case of emergency. |
| Name:      Title:      Position:       | Telephone number:      Cell phone number:       |
| 14. Provide the following information for ALL RESEARCH PERSONNEL involved in animal contact: *Hands On training is necessary if personnel have less than 1 year experience.* |
| Name:      | Role on Project. Qualifications and experience with the procedures used in the experiments:      | Number of years of experience with the specific species used in this experiment.      | ClearancesPolicy/Facility:Yes [ ]  No [ ] Health:Yes [ ]  No [ ] Wet Lab:Yes [ ]  No [ ] CITI Yes [ ]  No [ ]  |

|  |  |  |  |
| --- | --- | --- | --- |
| Name:      | Role on Project. Qualifications and experience with the procedures used in the experiments:      | Number of years of experience with the specific species used in this experiment.       | ClearancesPolicy/Facility:Yes [ ]  No [ ] Health:Yes [ ]  No [ ] Wet Lab:Yes [ ]  No [ ] CITI Yes [ ]  No [ ]  |
| Name:      | Role on Project. Qualifications and experience with the procedures used in the experiments:     : | Number of years of experience with the specific species used in this experiment.       | ClearancesPolicy/Facility:Yes [ ]  No [ ] Health:Yes [ ]  No [ ] Wet Lab:Yes [ ]  No [ ] CITI Yes [ ]  No [ ]  |
| Name:      | Role on Project. Qualifications and experience with the procedures used in the experiments:     : | Number of years of experience with the specific species used in this experiment.       | ClearancesPolicy/Facility:Yes [ ]  No [ ] Health:Yes [ ]  No [ ] Wet Lab:Yes [ ]  No [ ] CITI Yes [ ]  No [ ]  |

Each person with animal contact must have health clearance.

Collaborative Institutional Training Initiative’s (CITI)

All CUNY faculty members, postdoctoral scholars, graduate and undergraduate students involved in animal care, use or treatment must complete the CITI training in the care and use of animals prior to Institutional Animal Care and Use Committee (IACUC) approval of their protocol.

Log-in (or register if you are a first-time user) at https://www.citiprogram.org/Default.asp

 *Direction for registration can be found in the IACUC webpage.*

IACUC USE BELOW THIS LINE
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IACUC AUTHORIZATION

|  |
| --- |
| Approval:Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |