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| --- | --- |
| cuBLACK1_5_8 | Institutional Animal Care and Use Committee PROTOCOL APPLICATION FOR ANIMAL USE |

|  |  |
| --- | --- |
| Refer to the Instructions on the IACUC website: <http://www.creighton.edu/researchcompliance/iacuc/forms/>  | **Leave Blank – for Office Use** |
| **Protocol Number** | **USDA Category** | **Modification Number** | **Date Approved** |

Section A – Administrative Information

1. Principal Investigator (Last, First)

2. Project Title

3. Submission Type

[ ]  **New**

[ ]  **Renewal** Protocol number:

[ ]  **Modification** to open protocol Protocol number:

For a renewal, provide a brief summary below of the work completed under the existing protocol. Please indicate any uncompleted work that is to be carried over to the renewed protocol.

For a modification, provide a brief summary below of the changes requested and the reason(s) changes are needed. Use the track/change feature in Word to incorporate all necessary changes throughout this document and then send an electronic version to the IACUC office. Submit only section G for personnel changes. Once approved, a signed version will be requested.

4. Special Categories (check any that apply)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| [ ]  | Breeding only (no experiments) | [ ]  | Teaching only | [ ]  | Pilot study (approval is generally one year) |

5. Addenda

[ ]  This application includes one or more addenda, listed below.

6. Protocol Duration

Requested duration: [ ]  One year [ ]  Two years [ ]  Three years

Protocol duration begins on the date of approval by the IACUC. The protocol is reviewed at least annually for the period requested. Protocols may be closed early by contacting the IACUC office.

7. Grant Support

Funding support for protocol, if known. IACUC protocol and grant comparison is required upon “Just-in-Time” notification.

|  |  |  |  |
| --- | --- | --- | --- |
| Funding Agency: |       | Grant or contract number: |       |
| Submission Date: |       | Effective Date: |       |
| Title:  |       |

8. Record Keeping

List all locations where the records involving the animals in this protocol will be kept and how they can be made available for inspection by IACUC, USDA, PHS, or AAALAC personnel, if necessary.

9. Principal Investigator Certification

In signing this form, I certify that:

 The animals authorized for use in this protocol will be used only in the activities and in the manner described herein. Any changes in the procedures described must receive prior approval from the Institutional Animal Care and Use Committee (IACUC).

 The experiments described in this protocol do not unnecessarily duplicate previous experiments.

 For Category D or E procedures, alternatives have been thoroughly reviewed, and no valid alternatives to those procedures that may cause more than momentary slight pain, discomfort or distress (whether relieved or not) have been found.

 Current and future faculty, staff, students and visiting scientists who will participate in this protocol are qualified or will be adequately trained to conduct the described work in a humane manner. All personnel on the protocol will receive a copy of the approved protocol. I will notify IACUC when removing or adding personnel to this protocol and will not allow anyone to conduct any procedures under this protocol until they have met all IACUC training requirements.

 I will comply with Creighton’s Assurance of Compliance, the Creighton University Institutional Animal Care and Use Committee Policies and Procedures, the Animal Resource Facility’s Standard Operating Procedures, the Animal Occupational Health & Safety Procedures, the Animal Welfare Act, the Public Health Service Policy on Humane Care and Use of Laboratory Animals, the Guide for the Care and Use of Laboratory Animals, and all other Creighton University policies and procedures.

 **I understand that I am responsible for any and all activity conducted by me or my staff under this protocol. I further acknowledge that any failure to comply with federal, state or university requirements related to the use of animals may result in corrective action including, but not limited to, suspension of this protocol, destruction of data collected under this protocol, and/or termination of future rights to use animals at Creighton University.**

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Principal Investigator |  | Date |

**For IACUC Use Only:**

In signing this form, the IACUC Chair certifies that this [ ]  new/renewal / [ ]  modified protocol has been approved by the IACUC.

|  |  |  |
| --- | --- | --- |
|  |  |  |
| IACUC Chair |  | Date Signed |

In signing this form, the Attending Veterinarian certifies that the procedures meet with their approval. (new/renewal only)

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Attending Veterinarian |  | Date Signed |

Section B – Research Overview

1. Objectives

State the general aims of the proposed research, including the hypothesis(-es) and the anticipated benefits for human and/or animal welfare, or its contribution to basic knowledge. **Please use accessible language here and throughout the application so that non-scientists can understand your protocol – grant text is not appropriate.** *Federal regulations require that the IACUC include at least one non-scientist.*

2. Justification for Animal Use and Species Choice

It is understood that the use of animal models is generally preferable to the use of human subjects *The Animal Welfare Act requires the replacement of animals with non-animal systems or with less sentient animal species when possible without compromising the scientific objectives.*

Provide:

*i.* A justification of the use of live vertebrate animals rather than an alternative model (computer simulation, cell cultures, microorganisms, plants or invertebrates).

*ii.* The scientific rationale for the selection of the particular species and (if appropriate) strain(s) of vertebrates chosen.

3. Outline of Experimental Design

The outline should specify the experimental and control groups when applicable. Provide an overview of the procedures to be performed on each group, including endpoints (*e.g.*, euthanasia). (Detailed procedures are described in section E.) A timeline should be included when appropriate. List the variables being measured. For breeding, include a table of the strains and any crosses, and describe any culling plan.

4. Duplication

Does the work proposed duplicate previous work?

[ ]  Yes Explain why the duplication is necessary.

[ ]  Teaching only protocol – No additional explanation is necessary as duplication is expected in these protocols.

[ ]  Breeding only protocol – No additional explanation is necessary as duplication is expected in these protocols.

[ ]  Other – Please explain why duplication is scientifically necessary.

[ ]  No Indicate the basis of your answer (e.g. database search, journal review, scientific conferences).

Section C – Animal Numbers

1. Summary Animal Number Table

State the number of animals of each species and/or strain to be used in the study. Provide separate totals for the following categories, as applicable: 1) Experimental animals (post-natal animals used in experiments), 2) Breeders (animals to be used only to generate animals), 3) Excess animals (post-natal animals generated but not used in experiments; *e.g.* unwanted genotypes). **Note that all post-natal animals are counted for these purposes (unless they die naturally within a week of birth and before being used in any procedures). If the experiments use embryos, then fill in row below the table to tabulate the number of embryos.**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Species | Experimental Animals | Breeders | Excess Animals | Total |
|       |       |       |       |       |
|       |       |       |       |       |
|       |       |       |       |       |
| Total |       |       |       |       |
| Embryos |  |  |  |  |
|       |       | N/A |       |       |

2. Justification of Animal Numbers

Explain how the number of animals indicated above was determined. Your explanation should include a breakdown of the total numbers into experimental groups, sampling time points, etc., as relevant. We encourage the use of additional tables to facilitate presentation. When possible, the justification for sample sizes should include a power analysis with expected group differences and standard deviations; otherwise, provide alternative justification for animal numbers (*e.g.*, tissue yields). For breeding, indicate estimated yields of each experimental genotype. Estimate and explain any expected experimental failures or other losses. *The Animal Welfare Act requires reducing the number of animals to the minimum necessary to obtain scientifically valid data by optimizing experimental and statistical design (for example, more powerful statistical tests or power analyses to determine appropriate sample sizes).*

3. Acquisition and Primary Housing

List the source of all post-natal animals that will be procured or bred for this protocol. Embryos should not be included in this table. For Source, use “CV” to indicate that an accepted commercial vendor will be used, “Bred” to indicate breeding that is part of this protocol, and IACUC Protocol number to indicate transfer from a breeding protocol or an expiring protocol; if source is another institution, list the institution. See instructions for more information. For Primary Housing Location, use “ARF” for Animal Resource Facility; otherwise, specify room number.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Species/Strain | Source | TotalNumber from this Source | ApproximateDailyInventory | Primary HousingLocation |
|       |       |      |       |       |
|       |       |      |       |       |
|       |       |      |       |       |

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Section D – Animal Husbandry

1. Animal Care

Indicate who will provide care for animals and describe any care needs beyond the standard care provided by the Animal Resource Facility (ARF). Describe any special precautions required to reduce risk to animal care personnel from, for example, hazardous or infectious substances listed in section F.

[ ]  Standard animal care will be provided by ARF personnel.

[ ]  Standard animal care will be provided by ARF personnel except as described below.

Care:

Safety Precautions:

[ ]  All animal care will be provided by personnel listed on the protocol as described below.

Care:

Safety Precautions:

[ ]  Animals will not be housed under this protocol.

**Housing**: Social animals will be group housed unless scientific justification is provided.

[ ]  Animals will require temporary individual housing. Specify when and provide scientific justification (ie surgery, during specific treatment).

[ ]  Animals will require individual housing at all times. Provide scientific justification.

2. Animal Health

Indicate how general animal health, including absence of pain and distress, will be assessed. Include a description of the action(s) to be taken if animals experience unexpected pain, discomfort or distress, including criteria for euthanasia. (Methods of alleviating potential pain, discomfort or distress associated with experimental procedures should be discussed in sections E-6, E-7, and/or E-8, as appropriate.)

3. Deficits in Transgenic and Mutant Animals

**For strains of animals expected to experience more than slight pain or distress** (Category D or E) as a consequence of their genome, describe nature of the pain or distress, and the methods to be used to alleviate pain or discomfort associated with the deficit (Category D). Copy and paste to create multiple entries as needed. (Functional deficits due to procedures performed on animals should be discussed in Section E instead.)

Genotype:

Nature of deficit/plan of care:

Category of pain and distress (see section E-1): [ ]  Category D [ ]  Category E

For Category E genotypes only, explain the scientific necessity, and why relief cannot or will not be provided:

4. Disposition of Surviving Animals

Indicate the disposition (e.g., euthanasia, transfer to another protocol) of any animals for which the endpoints have not been specified as part of the experimental procedures (sections E-6, E-7, and/or E-8below).

Section E – Procedures

1. Category of Pain and Distress

Category identifiers reflect USDA standards, and category A is not used. For each procedure in E6, E7, and E8 check the box to indicate the appropriate USDA category. The same categories are used to classify deficits in animals due to genotype (D3).

**B** Breeding that involves no procedures or functional deficits that may cause more than momentary or slight pain, discomfort or distress.

**C** Research or teaching that involves no procedures or functional deficits that may cause more than momentary or slight pain, discomfort or distress.

**D** Research, teaching or breeding that has the potential to cause more than momentary or slight pain, discomfort or distress that will be alleviated with appropriate anesthesia, analgesia or tranquilizers and/or that involves chronic maintenance of animals with a minor to moderate functional deficit.

**E** Research, teaching or breeding involving more than momentary or slight pain, discomfort or distress that cannot or will not be alleviated through the administration of appropriate anesthetics, analgesics, or tranquilizers; and/or that involves chronic maintenance of animals with a severe functional deficit.

2. Euthanasia Methods

**List methods of euthanasia that are not part of a non-survival surgery.** (Non-survival surgery, including the mechanism of death, should be described in section E-7 or E-8. Non-survival surgery includes pre-mortem thoracotomy under anesthesia followed by perfusion of fixative.) Indicate the drug, gas, or physical method that will actually cause the death of the animal, as well as any preparatory anesthetic. For drug- or gas-based methods, give dosage and route of administration. For all methods that are not definitive, indicate how death will be verified (see instructions for more information). Justify the method of euthanasia if it is not classified as acceptable by the American Veterinary Medical Association. Provide the number of animals to be euthanized by each method, and the location (room number) where euthanasia will be performed.

|  |
| --- |
| [ ]  **Carbon Dioxide Euthanasia Following IACUC SOP** (Check box if using this method) |
| Delivery | Verification of Death | Number of Animals | Location of Procedure |
| Animals will be placed in a clear chamber with CO2 delivery at 20% of chamber volume per minute. | Animals will remain in chamber for 1 minute following cessation of all movements, including respiration. Death will be verified by the following physical method:       |       |       |

|  |
| --- |
| [ ]  **Drug and Inhalant-based Methods** (Check box if using this method) |
| Pharmaceutical gradeYes No\* | Agent | Dosage & Route | Physical Verification of Death / Additional Information | Number of Animals | Location of Procedure |
| **[ ]  [ ]**  |  |       |       |       |       |
| [ ]  [ ]  |       |       |       |       |       |
| \* | If any controlled substance is to be used, provide the Drug Enforcement Administration (DEA) registration number       and the name of the licensee.      If compound is not pharmaceutical grade (off the shelf, undiluted) then fill in section E6 below.  |

|  |
| --- |
| [ ]  **Physical Methods** (Check box if using this method) |
| Method | Additional Information | Number of Animals | Location of Procedure |
|       |       |       |       |
|       |       |       |       |

3. Anesthesia and Sedatives (Including Pre-anesthesia)

Drug choice and dosages must be appropriate for the species. Express dosage as quantity of active drug per g or kg of animal (for example mg/kg or ml/kg) rather than as volume of solution. Investigators are required to use *unexpired pharmaceutical grade* medications, when they exist, in all procedures on living animals, even terminal procedures.

|  |  |  |  |
| --- | --- | --- | --- |
| Pharmaceutical gradeYes No\* | Agent(s) | Dosage & Route | Verification of Anesthesia / Additional Information |
| **[ ]  [ ]**  |       |       |       |
| [ ]  [ ]  |       |       |       |
| \* | If any controlled substance is to be used, provide the Drug Enforcement Administration (DEA) registration number       and the name of the licensee.      If compound is not pharmaceutical grade (off the shelf, undiluted) then fill in section E6 below.  |

4. Analgesics

Include the frequency and duration of treatment and/or criteria to be used to assess analgesia requirements.

|  |  |  |  |
| --- | --- | --- | --- |
| Pharmaceutical gradeYes No\* | Agent | Dosage & Route | Frequency & Duration / Additional Information |
| **[ ]  [ ]**  |       |       |       |
| [ ]  [ ]  |       |       |       |
| \* | If any controlled substance is to be used, provide the Drug Enforcement Administration (DEA) registration number       and the name of the licensee.      If compound is not pharmaceutical grade (off the shelf, undiluted) then fill in section E6 below.  |

5. Drugs and Biological and Chemical Agents

Include any drugs or agents not already listed in E2-4 above.
For all hazardous and/or infectious drugs or agents complete Section F.

|  |  |  |  |
| --- | --- | --- | --- |
| Pharmaceutical gradeYes No\* | Agent | Dosage & Route | Frequency & Duration / Additional Information |
| **[ ]  [ ]**  |       |       |       |
| [ ]  [ ]  |       |       |       |
| \* | If any controlled substance is to be used, provide the Drug Enforcement Administration (DEA) registration number       and the name of the licensee.      If compound is not pharmaceutical grade (off the shelf, undiluted) then fill in section E6 below.  |

6. Non-pharmaceutical compounds used in live animals

List all compounds from E2-E5 that are non-pharmaceutical grade, this includes dilution of pharmaceutical grade drugs. Provide a) scientific rationale for use of each compound in animals, b) source of compound, grade/purity, c) formulation, and d) quality control to include sterility, pyrogenicity, stability, pH, osmolality, pharmacokinetics, physiological compatibility, and quality control. For Multiple agents create additional lines

|  |
| --- |
| Rationale :       |
| Source/Purity :       |
| Formulation:       |
| Quality Control:       |

7. Non-surgical Procedures

Provide the requested information for each procedure. Include plans for alleviation of discomfort or pain. Copy and paste to create multiple entries as needed.

Procedure name:

Description of procedure:

Category of pain and distress (see section E-1): [ ]  Category B/C [ ]  Category D [ ]  Category E

For Category E procedures only, explain the scientific necessity, and why relief cannot or will not be provided:

Location(s) where procedure will be performed:

[ ]  Animals will be kept in this location for more than 12 hours

Number of procedures to be performed: This procedure will be performed       times each on       animals for a total of       procedures performed during the project.

8. Rodent and Non-mammal Surgical Procedures

Categorize the surgical procedure(s) that will be performed on a single animal. See instructions for more information. (If the protocol includes groups of animals that undergo different sets of surgical procedures, check multiple boxes).

Surgical category: [ ]  Single non-survival [ ]  Single survival [ ]  Single survival followed by non-survival [ ]  Multiple minor [ ]  Multiple major (requires justification)

For multiple major surgeries only, explain the scientific necessity of performing multiple surgeries on a single animal:

Provide the information requested below for each procedure. Include plans for alleviation of discomfort or pain.
Copy and paste to create multiple entries as needed.

Procedure name:

Pre-operative procedures:

Description of surgery:

Post-operative procedures and care:

Category of pain and distress (see section E-1): [ ]  Category D [ ]  Category E

For Category E procedures only, explain the scientific necessity, and why relief cannot or will not be provided:

Location(s) where pre-and post-operative procedures will be done:

Location(s) where surgery will be performed:       [ ]  Animals will be kept in this location for more than 12 hours

Number of procedures to be performed: This procedure will be performed       times each on       animals for a total of       procedures performed during the project.

9. Non-rodent Mammal (NRM) Surgical Procedures

Categorize the surgical procedure(s) that will be performed on a single animal. See instructions for more information. (If the protocol includes groups of animals that undergo different sets of surgical procedures, check multiple boxes).

Surgical category: [ ]  Single non-survival [ ]  Single survival [ ]  Single survival followed by non-survival [ ]  Multiple minor [ ]  Multiple major (requires justification)

For multiple major surgeries only, explain the scientific necessity of performing multiple surgeries on a single animal:

Provide the information requested below for each procedure. Include plans for alleviation of discomfort or pain.
Copy and paste to create multiple entries as needed.

Surgical as well as pre- and post-operative procedures on non-rodent mammals should normally follow Creighton’s Standard Operating Procedures (SOPs). Minor modifications to these SOPs may be described and justified in this section. Significant modifications require the investigator to submit new SOPs. Describe specific procedures beyond those included in the SOPs. See instructions for more information.

Procedure name:

Standard Operating Procedures:

[ ]  NRM Surgery SOP will be followed as written (attach copy to Application).

[ ]  NRM Surgery SOP will be followed with minor modifications (attach copy to Application and describe below).

[ ]  Alternative SOP will be followed (attach copy to Application).

Description of modifications:

Specific procedure description:

Category of pain and distress (see section E-1): [ ]  Category D [ ]  Category E

For Category E procedures only, explain the scientific necessity, and why relief cannot or will not be provided:

Location(s) where pre-and post-operative procedures will be done:

Location(s) where surgery will be performed:       [ ]  Animals will be kept in this location for more than 12 hours

Number of procedures to be performed: This procedure will be performed       times each on       animals for a total of       procedures performed during the project.

10. Documentation of Lack of Alternatives to Category D or E Procedures

Describe the methods and sources used to determine that there are no scientifically acceptable alternatives to painful or distressful procedures identified in the procedures above. A search of at least one relevant database is recommended. (The Health Sciences Library Reference Librarian can assist you with these searches at no charge.) For each search, indicate a) the name of the database searched, b) date the search was performed, c) dates covered by the search, and d) key words and/or the search strategy used. See instructions for more information. *The Animal Welfare Act requires that you refine your experimental methods to minimize pain and distress (for example, through less-invasive surgical techniques, terminating experiments at earlier stages of morbidity), thereby enhancing animal well-being.*

Section F – Hazardous and Infectious Substances

Indicate any of the following that will be used in animals as part of the proposed protocol.

1. Biohazardous Materials

Substance or organism:

Risk group: [ ]  Exempt [ ]  RG-1 [ ]  RG-2 [ ]  RG-3 [ ]  RG-4

Required Animal Biosafety Level: [ ]  None [ ]  ABSL-1 [ ]  ABSL-2 [ ]  ABSL-3

IBC number:       (attach copy of registration document. Please note: Exempt status also requires IBC number)

Location(s) materials will be stored and used:

Special Animal Safety Protocol (SASP)

Additional information

2. Cell Cultures

Cell line or culture:

Source species:

Testing laboratory:       (attach copy of report)

Location(s) cultures will be used:

Special Animal Safety Protocol (SASP)

Additional information:

3. Carcinogens

Carcinogenic agents and their classification can be found at <http://monographs.iarc.fr/ENG/Classification/index.php>.

Substance:

IARC Classification: [ ]  Group 1 – Human Carcinogen
 [ ]  Group 2A – Probable Human Carcinogen
 [ ]  Group 2B – Possible Human Carcinogen

Location(s) agents will be stored and used:

Special Animal Safety Protocol (SASP)

Additional information:

4. Radioisotopes or Radiation Emitting Equipment

Substance or device:

RSC permit number:       (attach copy of permit)

Location(s) materials will be stored and used:

Additional information, including safety measures:

5. Other Hazardous Substances

Substance:

Nature of hazard:

Location(s) substances will be stored and used:

Special Animal Safety Protocol (SASP)

Additional information

|  |  |
| --- | --- |
| **Protocol Number** | **Date Approved** |

Section G – Personnel

(For personnel modifications to approved protocols submit section G only.
Use track changes to show additions and deletions)

1. Principal Investigator

|  |  |
| --- | --- |
| **Name (Last, First):** |  |
| Department or Institution: |       | Campus Phone: |       |
| E-Mail Address: |       | Emergency Phone: |       |
| Duties in project, including specific procedures listed in section E: |       |
| Experience or training specific to duties listed above: |       |
| Specify any additional training required and plan for completion:  |       |

2. Other Project Staff

|  |  |
| --- | --- |
| **Name (Last, First):** |  |
| Department or Institution: |       | Campus Phone: |       |
| E-Mail Address: |       | Emergency Phone: |       |
| Status: | [ ]  Co-investigator [ ]  Post-doc/Fellow [ ]  Technician [ ]  Graduate student [ ]  Undergraduate [ ]  Visiting scientist |
| Duties in project, including specific procedures listed in section E: |       |
| Experience or training specific to duties listed above: |       |
| Specify any additional training required and plan for completion:  |       |

|  |  |
| --- | --- |
| **Name (Last, First):** |  |
| Department or Institution: |       | Campus Phone: |       |
| E-Mail Address: |       | Emergency Phone: |       |
| Status: | [ ]  Co-investigator [ ]  Post-doc/Fellow [ ]  Technician [ ]  Graduate student [ ]  Undergraduate [ ]  Visiting scientist |
| Duties in project, including specific procedures listed in section E: |       |
| Experience or training specific to duties listed above: |       |
| Specify any additional training required and plan for completion:  |       |

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| **Name (Last, First):** |  |
| Department or Institution: |       | Campus Phone: |       |
| E-Mail Address: |       | Emergency Phone: |       |
| Status: | [ ]  Co-investigator [ ]  Post-doc/Fellow [ ]  Technician [ ]  Graduate student [ ]  Undergraduate [ ]  Visiting scientist |
| Duties in project, including specific procedures listed in section E: |       |
| Experience or training specific to duties listed above: |       |
| Specify any additional training required and plan for completion:  |       |

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| --- | --- |
| **Name (Last, First):** |  |
| Department or Institution: |       | Campus Phone: |       |
| E-Mail Address: |       | Emergency Phone: |       |
| Status: | [ ]  Co-investigator [ ]  Post-doc/Fellow [ ]  Technician [ ]  Graduate student [ ]  Undergraduate [ ]  Visiting scientist |
| Duties in project, including specific procedures listed in section E: |       |
| Experience or training specific to duties listed above: |       |
| Specify any additional training required and plan for completion:  |       |

3. For Modifications Only - Principal Investigator Certification

**If modifying the personnel list only, sign and submit just this section of the modified protocol.**

In signing this form, I certify that:

 Current and future faculty, staff, students and visiting scientists who will participate in this protocol are qualified or will be adequately trained to conduct the described work in a humane manner. All personnel on the protocol will receive a copy of the approved protocol. I will notify IACUC when removing or adding personnel to this protocol and will not allow anyone to conduct any procedures under this protocol until they have met all IACUC training requirements.

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Principal Investigator |  | Date |

**For IACUC Use Only:**

In signing this form, the IACUC Chair certifies that this [ ]  modified personnel form has been approved by the IACUC.

|  |  |  |
| --- | --- | --- |
|  |  |  |
| IACUC Chair |  | Date Signed |