|  |
| --- |
| **INSTRUCTIONS**:* Submit your completed application along with any required supplemental documentation (see Appendix A) to iacuc@une.edu for review.

***Note****: Modifications made to the Initial/De Novo IACUC Application and/or supplemental forms must be captured using track changes (****preferred method****), or highlighting the changes within the previously approved document.* * E-mail iacuc@une.edu for any questions you may have with regard to this form.
 |

|  |  |
| --- | --- |
| Version Date: | Enter date when form is first completed or date when form is last updated  |
| IACUC #: | Enter text |
| Project Title: | Enter text |

| 1. **ADMINISTRATIVE INFORMATION**
 |
| --- |
| **Principal Investigator Name¥**:Enter text | **You are**:[ ]  Faculty[ ]  Staff | **UNE Center or College**: | Enter text |
| **E-Mail**: | Enter text | **UNE Department**: | Enter text |
| **Phone #**: | Enter text |
|  |
| **Amendment Type**: *(select all that apply)*

|  |  |
| --- | --- |
| [ ]  Request change in personnel or personnel roles/responsibilities | Complete [Section B](#SectionB) |
| [ ]  Request increase in approved animal numbers | Complete [Section C](#SectionC) |
| [ ]  Request for additional animal strains and/or species | Complete [Section D](#SectionD) |
| [ ]  Request to add a new procedure or modify a previously approved procedure | Complete [Section E](#SectionE) |

 |
| ¥ | *Per the federal regulations, only one individual can be named as the Principal Investigator of the project. UNE students are NOT permitted to serve in the role of principal investigator.* |

| 1. **REQUEST CHANGE IN PERSONNEL OR PERSONNEL ROLES/RESPONSIBILITIES**
 |
| --- |
| 1. **Are you adding or removing personnel?** [ ]  No [ ]  Yes *(specify below)*

List the name(s) and e-mail address of the personnel to be added:Enter textList the name(s) of the personnel to be removed:Enter text |
| 1. **If this amendment adds new personnel, briefly describe their role(s) or responsibilities**:

***Note 1****: A change in the Principal Investigator cannot be administratively processed. It must be approved by the IACUC.****Note 2****: Specify the animal procedure(s) the new personnel will perform. For each procedure, indicate whether they will require training and/or supervision in order to conduct the procedure independently.* Enter text |
| 1. **Does this amendment include a change in role or responsibility for current personnel?** *(e.g., current personnel will be tasked with conducting additional animal procedures not previously documented in Supplemental Form A)*

***Note****: A change in the Principal Investigator cannot be administratively processed. It must be approved by the IACUC.* [ ]  No [ ]  Yes *(specify below any new animal procedure(s) the individuals will perform, and indicate whether they will require training and/or supervision in order to perform each specific procedure independently)*Enter text |
| 1. **Have applicable IACUC documents been revised to incorporate the requested change(s)?** [ ]  Yes [ ]  No

***Note 1****: All modifications to IACUC documents must be captured using track changes (****preferred method****), or highlighting the changes within the Word document.* ***Note 2****: Please refer below for the IACUC document that must be revised.*

|  |  |
| --- | --- |
| If the old version of the Initial/De Novo IACUC Application was last submitted for review… | If the new version of the Initial/De Novo IACUC Application was last submitted for review… |
| Complete Supplemental Form A: Study Team Training & Qualification Summary (Use Rev 1 or higher) | Revise Supplemental Form A: Study Team Training & Qualification Summary (Use Rev 1 or higher) |

 |

| 1. **REQUEST INCREASE IN APPROVED ANIMAL NUMBERS**
 |
| --- |
| 1. **Complete the table below**:

|  |  |
| --- | --- |
| 1. Total number of animals previously approved for use on this protocol:*(this represents the 3-year total number of animals encompassing all species)*
 | Enter text |
| 1. Additional number of animals needed for remainder of this project:
 | Enter text |
| 1. New total number of animals needed (Line 1 + Line 2):
 | Enter text |

 |
| 1. **Indicate the common name (and strain if applicable) of the additional animals required for the remainder of this project.**

Enter text |
| 1. **Provide a justification for the requested increase in the number of approved animals.**

***Note****: The justification must be based on one of the following: (A) statistical power calculations (****provide details****), (B) past experience of the investigator, or (C) search of the relevant literature where more than one report has used the same or similar techniques to those proposed in the protocol (****briefly discuss the result of the search****).* Enter text |
| 1. **Have applicable IACUC documents been revised to incorporate the requested change(s)?** [ ]  Yes [ ]  No

***Note 1****: All modifications to IACUC documents must be captured using track changes (****preferred method****), or highlighting the changes within the Word document.* ***Note 2****: Please refer below for IACUC documents that must be revised.*

|  |  |
| --- | --- |
| If the old version of the Initial/De Novo IACUC Application was last submitted for review… | If the new version of the Initial/De Novo IACUC Application was last submitted for review… |
| **Indicate the sections of the old Initial/De Novo IACUC Application that have been revised**:[ ]  **Section D** (Animal Requirements)[ ]  **Section G** (Rationale for Animal Use)[ ]  **Section H** (Description of Experimental Design & Animal Procedures) | **Indicate the sections of the new Initial/De Novo IACUC Application that have been revised**:[ ]  **Section C** (Animal Requirements)[ ]  **Section F** (Justification of Animal Numbers)[ ]  **Section G** (Description of Experimental Design & Animal Procedures) |

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| 1. **REQUEST FOR ADDITIONAL ANIMAL STRAINS AND/OR SPECIES**
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| --- |
| 1. **You are requesting**: *(select all that apply)*

[ ]  The addition of a new species[ ]  The addition of a new strain |
| 1. **Specify the new species and/or strain(s) needed for this project.**

Enter text |
| 1. **Provide the rationale for why the new species and/or strain(s) are requested for this project.**

Enter text |
| 1. **Will this amendment include the use of any genetically modified animals?** [ ]  No [ ]  Yes *(see note below)*

*If ‘Yes’, please revise the Initial/De Novo IACUC Application to address the following items: (A) describe any phenotypic consequences of the genetic manipulations to the animals, and any special care or monitoring that the animals will require, and (B) specify if the IBC has been consulted or contacted.*  |
| 1. **Specify the specific source(s) of the requested animals.** *(e.g., name of vendor or investigator and institution name; for field work or wildlife studies indicate the location where animals will be studied and/or captured)*

Enter text |
| 1. **Has the appropriate facility manager (fish or rodent) been consulted to determine if the facility has the resources and capability to support the activities outlined in this amendment?**

***Note****: For field work or wildlife studies involving fish, please consult with the GMSC Fish Facility Manager* ***before*** *submitting your amendment, regardless of whether fish will be housed at UNE.*[ ]  N/A *(field work or wildlife study NOT involving fish)* [ ]  No [ ]  Yes *(specify date below)***Date of Consult**: Enter text |
| 1. **Will animals affected by this amendment be housed in the field, a lab, or anywhere else outside the central facility for more than 12 hours?** [ ]  No [ ]  Yes *(see note below)*

*If ‘Yes’, please revise the Initial/De Novo IACUC Application or Supplemental Form E to provide details.* |
| 1. **Provide a response to the following items**:
2. Will you be using equipment ***and*** space within the UNE Behavior Core? [ ]  No [ ]  Yes *(see note below)*
3. Will you be using space only (no equipment) within the UNE Behavior Core? [ ]  No [ ]  Yes *(see note below)*
4. Will you need assistance from any personnel from the UNE Behavior Core? [ ]  No [ ]  Yes *(see note below)*

*If you answered ‘Yes’ to any of the above questions, you must consult with the Behavior Core (*[*BehaviorCore@une.edu*](BehaviorCore%40une.edu)*)* ***before*** *submitting your amendment for IACUC review.* **Date of Behavior Core Consult**: Enter text |
| 1. **Have applicable IACUC documents been revised to incorporate the requested change(s)?** [ ]  Yes [ ]  No

***Note 1****: All modifications to IACUC documents must be captured using track changes (****preferred method****), or highlighting the changes within the Word document.* ***Note 2****: Please refer below for IACUC documents that must be revised.*

|  |  |
| --- | --- |
| If the old version of the Initial/De Novo IACUC Application was last submitted for review… | If the new version of the Initial/De Novo IACUC Application was last submitted for review… |
| **Indicate the sections of the old Initial/De Novo IACUC Application that have been revised**:[ ]  **Section D** (Animal Requirements)[ ]  **Section G** (Rationale for Animal Use) as necessary[ ]  **Section H** (Description of Experimental Design & Animal Procedures) | **Indicate the sections of the old Initial/De Novo IACUC Application that have been revised**:[ ]  **Section C** (Animal Requirements)[ ]  **Section E** (Species & Strain Justification)[ ]  **Section G** (Description of Experimental Design & Animal Procedures)**Indicate the supplemental forms that have been revised**:[ ]  **Supplemental Form D**: Use of Biological Materials, Chemicals, Drugs, Hazardous Agents, or Other Substances in Animal Studies[ ]  **Supplemental Form E**: Field Work & Wildlife Studies |

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| 1. **REQUEST TO ADD A NEW PROCEDURE OR MODIFY A PREVIOUSLY APPROVED PROCEDURE**
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| --- |
| 1. **Using *plain language that a non-scientist would understand*, briefly describe the procedure(s) that you wish to add or modify.**

Enter text |
| 1. **Provide the rationale for why you are requesting the proposed change in procedure(s).**

Enter text |
| 1. **Are all personnel who will perform any new or revised procedures identified in Supplemental Form A, and are they are appropriately trained–or will they be trained–before conducting the procedure(s)?**

[ ]  Yes [ ]  No *(complete* [*Section B*](#SectionB) *of this form)* |
| 1. **Are you proposing a new or modified surgical procedure?** [ ]  No [ ]  Yes *(answer the questions below)*

*If ‘Yes’, please revise the Initial/De Novo IACUC Application (surgery section) or Supplemental Form C (Animal Surgical Procedures) to identify and describe the new or modified surgical procedure(s) to be performed.* 1. Identify the location where the new or modified surgical procedure will be performed. *[e.g., building(s) and room(s), GPS coordinates or general region for field work or wildlife studies]*

Enter text1. For animals who will undergo the new or modified surgical procedure(s), select all that apply:

[ ]  Animals will recover from anesthesia following surgery[ ]  Animals will be euthanized before recovery from anesthesia[ ]  Animals will be administered a paralytic agent during surgery *(****describe below****)*[ ]  Animals have experienced a previous survival surgery ***before*** being placed in this project *(****describe below****)*[ ]  Animals will undergo multiple survival surgeries as part of this project *(****describe below****)*Enter text |
| 1. **Do the new or modified procedures fall under USDA pain category D or E?**

***Category D****: Procedures involving pain or distress to animals are appropriately relieved with anesthetics, analgesics, and/or tranquilizers or other methods for relieving pain or distress.****Category E****: Procedures involving pain or distress or potential pain and distress to animals that are* ***NOT*** *relieved with anesthetics, analgesics and/or tranquilizer drugs or other methods for relieving pain or distress.*[ ]  No [ ]  Yes *(answer the questions below)*1. Has the Initial/De Novo IACUC Application been revised to incorporate the following items below (as applicable)? [ ]  Yes [ ]  No *(explain below)*
* A description of your consideration and determination that alternative procedures are not available or cannot be used.
* If the new or modified procedure is classified under USDA pain category E, you have provided a scientific justification to explain why the use of anesthetics, analgesics, sedatives, or tranquilizers cannot be used to relieve pain or distress in animals.

Enter text1. List the databases that were searched to determine if alternatives exist to procedures that cause pain or distress in animals, and provide the range of the search and keywords used in the search.

***Note****: At least two reference sources must be listed, and the date range should include the past 5-10 years.*Enter text1. For new or modified procedures that fall under USDA pain category D or E, the UNE attending veterinarian, Dr. Arthur Lage, MUST be consulted prior to submitting this amendment. *Dr. Lage can be contacted at* *artlage123@gmail.com* *or (617) 699-2256.*

**Date of Veterinarian Consult**: Enter text |
| 1. **Do the new or modified procedures involve the addition or modification of any of the following?**

***Note****: If you answer ‘Yes’ to any item below, you must update the appropriate section of your Initial/De Novo IACUC Application (Chemicals & Other Materials section), or Supplemental Form D (Use of Biological Materials, Chemicals, Drugs, Hazardous Agents, or Other Substances in Animal Studies).* Select all that apply:[ ]  Use of routinely administered drugs, biologics, or compounds[ ]  Use of non-pharmaceutical grade drugs, biologics, or compounds[ ]  Use of halogenated inhalant agents (e.g., isoflurane)[ ]  Use of controlled substances[ ]  A change in the Animal Biosafety Level (ABSL)[ ]  Use of radioactive materials[ ]  Use of biological material or human or animal products for use in laboratory rodents (e.g., cells or cell lines, antigens, antisera)[ ]  Use of new investigational compounds or drugs[ ]  A change in practices or procedures for the safe handling and disposal of contaminated animals and materials[ ]  None of the above |
| 1. **Do the new or modified procedures involve the use transgenic animals and/or hazardous or potentially hazardous materials?** *(e.g., biological agents, recombinant DNA, hazardous chemicals, radioactive materials)*

***Note****: The use of transgenic animals and/or hazardous or potentially hazardous materials may require consultation and/or approval as necessary from UNE Environmental Health & Safety (*[*EH&S*](https://www.une.edu/campus/ehs)*), Institutional Biosafety Committee (*[*IBC*](https://www.une.edu/research/integrity/institutional-biosafety-committee)*), and/or the Radiation Safety Officer (*[*RSO*](https://www.une.edu/campus/ehs/laboratory-safety/radiation-safety)*)* ***before*** *IACUC approval can be granted.*[ ]  No [ ]  Yes *(answer the question below)*1. Provide the information outlined in the table below with respect to the new or modified procedure(s):

| Category & Contact Person | Name of Agent/Material or Organism | Consultation & Approval Status*(select all that apply)* | Other Details *(e.g., Committee Tracking #, consult date)* |
| --- | --- | --- | --- |
| Biological Agents (IBC) | Enter text | [ ]  IBC Consulted[ ]  IBC Not Consulted[ ]  Pending Approval[ ]  Approved | Enter text |
| Recombinant DNA (IBC) | Enter text | [ ]  IBC Consulted[ ]  IBC Not Consulted[ ]  Pending Approval[ ]  Approved | Enter text |
| Hazardous Chemicals(EH&S) | Enter text | [ ]  EH&S Consulted[ ]  EH&S Not Consulted | Enter text |
| Radioactive Materials(RSO) | Enter text | [ ]  RSO Consulted[ ]  RSO Not Consulted | Enter text |
| Transgenic Animals (IBC) | Enter text | [ ]  IBC Consulted[ ]  IBC Not Consulted[ ]  Pending Approval[ ]  Approved | Enter text |
| Other | Enter text | Enter text | Enter text |

 |
| 1. **Have applicable IACUC documents been revised to incorporate the requested change(s)?** [ ]  Yes [ ]  No

***Note 1****: All modifications to IACUC documents must be captured using track changes (****preferred method****), or highlighting the changes within the Word document.* ***Note 2****: Please refer below for IACUC documents that must be revised.*

| If the old version of the Initial/De Novo IACUC Application was last submitted for review… | If the new version of the Initial/De Novo IACUC Application was last submitted for review… |
| --- | --- |
| **Indicate the sections of the old Initial/De Novo IACUC Application that have been revised**:[ ]  **Section B** (Veterinary Consult)[ ]  **Section C** (Training in Procedures)[ ]  **Section E** (Transportation)[ ]  **Section F** (Study Objectives)[ ]  **Section H** (Description of Experimental Design & Animal Procedures)[ ]  **Section I** (Literature Search)[ ]  **Section J** (Surgery)[ ]  **Section K** (Pain or Distress Classification & Consideration of Alternatives)[ ]  **Section L** (Inhalant, Oral, Topical, or Injectable Drugs)[ ]  **Section M** (Method of Euthanasia or Disposition of Animals at End of Study)[ ]  **Section N** (Chemicals & Other Materials)[ ]  **Section O** (Biological Material/Animal Products for Use in Animals)[ ]  **Section P** (Field Studies)[ ]  **Section Q** (Special Concerns or Requirements of the Study) | **Indicate the sections of the new Initial/De Novo IACUC Application that have been revised**:[ ]  **Section B** (Lay Summary)[ ]  **Section G** (Description of Experimental Design & Animal Procedures)[ ]  **Section H** (Transportation of Animals)[ ]  **Section I** (Pain & Distress Classification & Considerations of Alternative Procedures)[ ]  **Section J** (Method of Euthanasia or Disposition of Animals)[ ]  **Section K** (Special Concerns or Requirements)**Indicate the supplemental forms that have been revised**:[ ]  **Supplemental Form A**: Study Team Training & Qualification Summary[ ]  **Supplemental Form C**: Animal Surgical Procedures[ ]  **Supplemental Form D**: Use of Biological Materials, Chemicals, Drugs, Hazardous Agents, or Other Substances in Animal Studies[ ]  **Supplemental Form E**: Field Work & Wildlife Studies[ ]  **Supplemental Form F**: Teaching & Course Activities Involving Live Animals |

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**Appendix A: Submission Checklist**

| REQUIRED SUPPLEMENTAL DOCUMENTATION | Yes |
| --- | --- |
| 1 | IACUC Amendment Attestation Form |[ ]
| 2 | Revised Initial/De Novo IACUC Application and supplemental forms (as necessary)* *All modifications to IACUC documents must be captured using track changes (****preferred method****), or highlighting the changes within the Word document*
 |[ ]

|  |
| --- |
| **Applicant Remarks:** |
| Enter text |