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| **INSTRUCTIONS**:   1. Complete the **Submission Checklist** located in [Appendix A](#AppendixA) to determine what documents aside from this form are required as part of your application. 2. Please reference the ‘**Guidance for Completing the Application for Initial & *De Novo* IACUC Review**’ available on the UNE IACUC [website](https://www.une.edu/research/integrity/iacuc) for assistance with completing your responses for this application. 3. Submit your completed application along with any required supplemental documentation to [iacuc@une.edu](mailto:iacuc@une.edu) for review.   Contact the IACUC at [iacuc@une.edu](mailto:iacuc@une.edu) for any questions you may have with regard to your proposed animal activity or the application process. |

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

| 1. **ADMINISTRATIVE INFORMATION** | | | | | |
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| **Principal Investigator Name[[1]](#footnote-1)**:  Enter text | | **You are**:  Faculty  Staff | **Estimated Start Date**: | | Enter text |
| **Estimated End Date**: | | Enter text |
| **E-Mail**: | Enter text | **UNE Center or College**: | | Enter text |
| **Phone #**: | Enter text | **UNE Department**: | | Enter text |
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| 1. **Submission Type**:   Initial Submission  *De Novo* Submission  *If De Novo review is requested, please record your previously assigned IACUC # below:*  Enter text | | | | 1. **Funding Type**: *(select all that apply)*   Federal *(specify source below)*  State of Maine *(specify source below)*  UNE Internal Award  Other/Private *(specify source below)*  Not Funded  Enter text | |
| 1. **Protocol Type**: *(select all that apply)*   Research  Teaching  Testing *(e.g., toxicology studies, pharmaceutical, medical device, or product development testing)*  Breeding  Other *(specify below)*  Enter text | | | | 1. **Project Attributes**:*(select all that apply)*   Use of laboratory animals  *(e.g., mice, rats, zebrafish)*  Use of wild animals  *(e.g., field work or wildlife study)*  Other *(specify below)*  Enter text | |
| 1. **Is this a *De Novo* submission?**  No  Yes *(answer the questions below)*   ***Note****: As part of the De Novo (3-year renewal) submission, you are asked to provide a summary of the results from the previous approval period – even if you have submitted annual progress reports in years one and two. This information helps the IACUC evaluate the overall outcomes of the completed protocol, assess the scientific justification for continued animal use, and identify opportunities to refine procedures in accordance with the principles of Replacement, Reduction, and Refinement (the 3Rs). A cumulative summary ensures the committee has a comprehensive understanding of the project’s impact and progress before approving a new 3-year period of work.*   1. Provide a brief summary of the results obtained during the previous 3-year approval period (especially the last year). How did these results contribute to the overall project goals?   Enter text   1. Did the project meet its specific aims during the previous 3-year approval period? If not, please explain any deviations and the reasons.   ***Note****:**If the original scientific aims or objectives of the project changed during the previous approval period, please describe the changes and the reasons for them.*  Enter text   1. Have there been any significant amendments (e.g., changes in species, procedures, drug regimens, personnel) to this protocol during the previous 3-year approval period?   ***Note****:**A significant amendment is any change to an approved protocol that affects animal welfare (including refinements that reduce animal use or improve welfare), alters the scientific goals of the project, or involves changes to the qualifications of key personnel.*  No  Yes *(briefly summarize in 1-2 sentences below)*  Enter text   1. Were there any unanticipated outcomes, adverse events, or significant welfare concerns involving the animals during the previous 3-year approval period? If yes, explain how they were addressed.   Enter text   1. Please summarize the number of animals actually used during the previous 3-year approval period, compared to the total number approved (including any amendments). If there were significant differences, explain the reasons. How has this informed your estimate of animal numbers for the proposed renewal?   Enter text   1. Based on the results and experience from the previous 3-year approval period, are you proposing any refinements or changes to procedures, animal numbers, or endpoints?   Enter text   1. Have you published or presented findings related to this protocol during the previous 3-year approval period?   ***Note****:**You may submit a CV/biosketch, list citations, or provide a few key examples.*  No  Yes *(briefly describe below or submit an attachment)*  Enter text | | | | | |
| 1. **Export Control**:   ***Note****: The following screening questions are being asked to assess whether your project may be subject to U.S. export control regulations. These questions aim to determine if foreign individuals may have access to project technology or information regulated under these laws.*   1. Will any foreign persons participate in this project as sponsors, collaborators, or staff?  No  Yes 2. Will any hardware, software, substances, information or data for this project be exported out of the U.S. or transferred to foreign persons within the U.S.?  No  Yes | | | | | |

| 1. **LAY SUMMARY (~300 Words)** |
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| **Using *plain* *language that a non-scientist would understand*, briefly explain the objectives of the project and why the project is important to human or animal health, the advancement of knowledge, or the good of society.**  Enter text |

| 1. **ANIMAL REQUIREMENTS** |
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1. **Please complete the following tables**:

***Note****: For field work or wildlife studies, please list only the target species in the tables below. Do not include any anticipated non‑target species (bycatch).*

| Common & Scientific Name  of Animal *(e.g., Mouse; Mus musculus)* | Strain/Subspecies *(e.g., C57BL6)* | Sex *(e.g., M/F)* | Approximate Age, Weight,  or Size of Animal | Total # of Animals  Needed for Project |
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| Common Name of Animal | Number of *NEW* Animals Planned to be Used Each Year | | | 3 Year Total # of Animals |
| --- | --- | --- | --- | --- |
| Year 1 | Year 2 | Year 3 |
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| 1. **Specify the specific source(s) of the animal(s) identified in the tables above (e.g., name of vendor or investigator and institution name)**:   ***Note****: For field work or wildlife studies, please skip this question.*  Enter text |
| 1. **Does this project involve the use of genetically modified animals?**  No  Yes *(answer the questions below)* 2. Has the IBC been contacted or consulted?  Yes  No *(explain below)*   Enter text   1. Has an IBC tracking # been assigned to this project yet?  No  Yes *(indicate IBC # below)*   Enter text   1. Describe any phenotypic consequences of the genetic manipulations to the animals, and any special care or monitoring that the animals will require.   Enter text |
| 1. **Specify the primary location(s) where animals will be housed for this project**:   ***Note****: For field work or wildlife studies, please skip this question.*  Enter text |
| 1. **Specify the location(s) where non-surgical animal procedures (e.g., behavior testing) will be conducted for this project:**   ***Note****: For field work or wildlife studies, please skip this question.*  Enter text |
| 1. **Has the appropriate facility manager (fish or rodent) been consulted to discuss the details of this project?**   ***Note 1****: Before housing animals at UNE, a consultation is required to assess whether the facility has the necessary resources and capacity to support the proposed project.*  ***Note 2****: For field work or wildlife studies involving fish, please consult with the GMSC Fish Facility Manager* ***before*** *submitting your IACUC application, regardless of whether fish will be housed at UNE.*  No  Yes *(specify date below)*  **Date of Consult**: Enter text |
| 1. **Will animals be housed in the field, a lab, or anywhere else outside the central facility for more than 12 hours?**   No  Yes *(provide details below – e.g., UNE building and room number)*  Enter text |

| 1. **RATIONALE FOR ANIMAL USE** |
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| **Explain your rationale for animal use, including the reasons why non-animal models cannot be used**:  Enter text |

| 1. **SPECIES & STRAIN JUSTIFICATION** |
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| **Justify the appropriateness of the animal species and strain(s) selected for this project**:***Note****: The species selected should be the lowest possible on the phylogenetic scale.*  Enter text |

| 1. **JUSTIFICATION OF ANIMAL NUMBERS** |
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| **Justify the number of animals requested to be used for this project**.   * *The number of animals should be the minimum number required to obtain statistically valid results.* * *Please refer to the ‘****Guidance for Completing the Application for Initial & De Novo IACUC Review****’ (click* [*here*](https://www.une.edu/research/integrity/iacuc)*) for assistance with this section.*   Enter text |

| 1. **DESCRIPTION OF EXPERIMENTAL DESIGN & ANIMAL PROCEDURES** |
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| 1. **Will this project involve any animal procedures listed in the IACUC-approved Behavior Core Service Book?**   No  Yes *(answer the question below)*   1. Will the animal procedure(s) be conducted per the Behavior Core Service Book without modification?   Yes *(see Note 1 below)*  No *(see Note 2 below)*  ***Note 1****:**If animal procedures will be carried out according to the Behavior Core Service Book without any modifications, you do NOT need to provide a written description of the procedure(s) in Question 2 below. Instead, simply reference the Behavior Core procedure(s) that will be used in the project.*  ***Note 2****:**If modified Behavior Core animal procedures will be used, a written description of the modified procedure(s) MUST be provided in Question 2 below.* |
| 1. **Briefly explain the experimental design and specify all animal procedures***.*  * *To the degree possible, this section should be written in plain language that a non-scientist would understand.* * *The description should allow the IACUC to understand the experimental course of an animal from its entry into the experiment to the endpoint of the project.* * *If the project involves sequential events, the sequence, time intervals, and other relevant details should be clearly described.* * *The USDA pain category must be documented for each animal procedure, except when an unmodified Behavior Core Service Book procedure is referenced.* * *For examples and guidance on completing this section, please refer to the ‘****Guidance for Completing the Application for Initial & De Novo IACUC Review****’ (click* [*here*](https://www.une.edu/research/integrity/iacuc)*).*   ***Note****: In lieu of providing details within this section, the experimental design and animal procedures may be summarized within a separate* ***Word*** *document to accompany this application.*  Enter text |

| 1. **TRANSPORTATION OF ANIMALS** |
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| 1. **Will live animals be transported outside UNE premises (e.g., via personal vehicle, commercial carrier, public roads, waterways, or out of state)?**   ***Note****: For field work or wildlife studies, please skip this question.*  No  Yes *(answer the question below)*   1. Describe the mode of transport (personal or commercial), duration, handling procedures, and measures taken to ensure animal welfare and regulatory compliance during transit and upon receipt:   Enter text |
| 1. **Will the project require animals to be transported between rooms or buildings (e.g., behavior testing) at UNE?**   No  Yes *(answer the questions below)*   1. Describe the method, schedule, and route of transportation:   Enter text   1. What measures will be taken to minimize stress and discomfort during and after transportation?   ***Note****: Appropriate measures to consider include use of proper transport containers, temperature and environmental controls, minimizing noise and vibrations, minimizing the duration of transport, familiarizing animals with transport containers, monitoring animals during and after transport, and use of trained personnel.*  Enter text |
| 1. **Will animals be permanently moved from their original housing location to a different location within UNE?**   No  Yes *(enter the date the applicable facility manager (fish or rodent) was consulted below)*  **Date of Consult**: Enter text |

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| 1. **PAIN & DISTRESS CLASSIFICATION & CONSIDERATION OF ALTERNATIVE PROCEDURES** |
| 1. **Do any animal procedures fall under USDA pain category D or E?**  No  Yes *(answer the questions below)*   ***Category D****: Procedures involving pain or distress to animals are appropriately relieved with anesthetics, analgesics, an/or tranquilizer drugs 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.*   1. Describe your consideration of alternatives and your determination that alternative procedures are not available or cannot be used. *Alternatives include methods that refine existing tests by minimizing animal distress, reduce the number of animals necessary for an experiment, or replace whole-animal use with in vitro or other tests.*   Enter text   1. If your project involves USDA category D procedures, are all drugs (e.g., anesthetics, analgesics, sedatives, tranquilizers) that will be used to relieve pain or distress outlined in ‘***Supplemental Form D: Use of Biological Materials, Chemicals, Drugs, Hazardous Agents, or Other Substances in Animal Studies***’?   N/A  Yes  No   1. If your project involves USDA category E procedures, provide 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 text   1. List the databases that were searched to determine if alternatives exist to procedures that cause pain or distress in animals, and provide the date 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 text   1. For procedures involving USDA category D or E activities, the UNE attending veterinarian, Dr. Arthur Lage, MUST be consulted prior to submitting this application. *Dr. Lage can be contacted at* [*artlage123@gmail.com*](mailto:artlage123@gmail.com) *or (617) 699-2256.*   **Date of Veterinary Consult**: Enter text |

| 1. **METHOD OF EUTHANASIA & DISPOSITION OF ANIMALS** |
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| 1. **Will the project involve planned euthanasia and/or the possibility of unplanned euthanasia of animals?**   No  Yes *(answer the questions below)*  ***Note****: This section MUST be completed for field work or wildlife studies that involve the capture/handling/restraint of wild animals, even when planned euthanasia is not part of the protocol. Having a contingency plan for unplanned euthanasia is necessary to ensure the humane treatment of animals in case of unexpected injury or distress during the project.*  ***Planned euthanasia*** *refers to the intentional and humane termination of an animal’s life as part of the protocol. It is typically carried out at a predetermined time or under specific circumstances outlined in the experimental design, in order to minimize pain or distress to the animal, and to meet the scientific objectives of the project.*  ***Unplanned euthanasia*** *refers to the unexpected or unscheduled euthanasia of an animal due to unforeseen circumstances, such as injury, illness, or distress that occurs during the course of the project. Euthanasia is implemented when it becomes clear that the animal is suffering or has reached a state where its well-being cannot be maintained, and further survival is not viable or ethical.*   1. Describe the primary (and secondary, if applicable) method(s) of euthanasia to be used:   ***Note****: If a chemical agent is used, specify the dosage and route of administration.*  Enter text   1. Is the described method of euthanasia recommended by the AVMA guidelines (click [here](https://www.avma.org/resources-tools/avma-policies/avma-guidelines-euthanasia-animals))?   Yes  No *(provide a scientific justification below why this method must be used)*  Enter text   1. Describe how animal death will be confirmed following euthanasia:   Enter text   1. Describe the method of carcass storage/disposal:   ***Note****: For field work or wildlife studies, consider how carcass disposal might affect scavenger species and avoid methods that could lead to negative consequences, such as attracting dangerous predators or poisoning other wildlife.*  Enter text |

| 1. **SPECIAL CONCERNS OR REQUIREMENTS** |
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| 1. **Describe any special housing, equipment, animal care, or any departures from the** [***Guide***](https://olaw.nih.gov/resources/publications/guide-care-2011.htm):   *For example, special caging, water, feed, waste disposal, environmental enrichment, etc.*  Enter text |
| 1. **Describe the contingency plan if a pregnant animal is unexpectedly acquired for the project**:   *For example, will any special husbandry procedures need to be employed? What will happen to the offspring – will they be kept or euthanized? If offspring will be euthanized, does the method of euthanasia differ from what is described in Section J above?*  Enter text |
| 1. **Will this project involve the use of fish to be housed at UNE?**  No  Yes *(answer the questions below)* 2. What is the appropriate stocking density (fish/gallon) for the intended species and the maximum potential stocking density for this project? Please include at least one citation or reference in your response below.   Enter text   1. Will more than one species to be housed in the same environment together?  No  Yes *(explain below)*   If ‘Yes’, please provide at least one citation or reference that justifies the species being housed together. If no such citation or reference exists, explain how the husbandry of each species allows them to be housed together (e.g., water quality parameters, wild population habitat, predation, etc.).  Enter text   1. Specify what water quality parameters will be measured, how often, and the appropriate range for each parameter and each species. Please include at least one citation or reference in your response below.   ***Note****: Examples of water quality parameters include dissolved oxygen, temperature, pH, salinity, ammonia,* *conductivity, nitrite, alkalinity, phosphorous, nitrate, etc.*  Enter text |
| 1. **Will this project involve the use of laboratory mice or rats?**  No  Yes *(answer the questions below)* 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](https://une1.sharepoint.com/sites/InstitutionalReviewBoard-IRBAdministration/Shared%20Documents/IRB%20Administration/Document%20Control/Revision%20History/RES-F-011/BehaviorCore@une.edu)) ***before*** submitting your application for IACUC review.  **Date of Behavior Core Consult**: Enter text |

**Appendix A: Submission Checklist**

| REQUIRED SUPPLEMENTAL DOCUMENTATION *(as applicable to your project type)* | | Yes | N/A |
| --- | --- | --- | --- |
| 1 | Supplemental Form A: Study Team Training & Qualification Summary **[Required]** |  |  |
| 2 | Supplemental Form B: Principal Investigator Certification **[Required]** |  |
| 3 | Supplemental Form C: Animal Surgical Procedures |  |  |
| 4 | Supplemental Form D: Use of Biological Materials, Chemicals, Drugs, Hazardous Agents, or Other Substances in Animal Studies |  |  |
| 5 | Supplemental Form E: Field Work & Wildlife Studies |  |  |
| 6 | Supplemental Form F: Teaching & Course Activities Involving Live Animals |  |  |
| 7 | A summary of the experimental design and animal procedures in a stand-alone **Word** document *(if details are NOT documented within Section G of this application)* |  |  |
| 8 | Attach a copy of any IACUC-approved laboratory SOPs that have been referenced within this application or within any required supplemental forms  ***Note***: *You do NOT need to be include a copy of the IACUC-approved Behavior Core Service Book with your application.* |  |  |
| 9 | Copy of required federal, state, and/or local permits or licenses necessary to conduct the proposed animal activities (e.g., wildlife collection permits, endangered or protected species permits, import/export licenses for transporting animals across borders or states) |  |  |

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

1. *In accordance with federal regulations, only one individual can be designated as the principal investigator for the protocol. UNE students are NOT permitted to serve in the role of principal investigator.* [↑](#footnote-ref-1)