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| **INSTRUCTIONS**:* Complete this form and supply a copy of any laboratory SOPs referenced in your responses for IACUC review.
* Contact the Office of Research Integrity at iacuc@une.edu for any questions you may have with regard to this form.
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| Version Date: | Enter date when form is first completed or date when form is last updated  |
| Principal Investigator: | Enter text |
| IACUC #: | Enter ‘To Be Determined’ if IACUC # not assigned yet |
| Study Title: | Enter text |

| 1. CHECKLIST
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**Complete the table below to determine which section(s) of this form apply to your study.**

| Description of Substance | Does your study involve the use of the described substance(s)? | If ‘Yes’… |
| --- | --- | --- |
| Drugs, biologics, or other compounds routinely administered to animals such as: * Analgesics
* Anesthetics
* Sedatives or tranquilizers
* Antibiotics
* Euthanasia agents
* Controlled substances
* Vaccines
 | [ ]  No [ ]  Yes | Complete section ‘**B: Use of Routinely Administered Drugs, Biologics, or Other Compounds**’ |
| Use of hazardous or potentially hazardous substances such as:* Infectious agents *(e.g., bacteria or viruses)*
* Radioactive materials
* Biological toxins
* Viral vectors
* Hazardous chemicals *(e.g., toxic, flammables, corrosives, irritants, mutagens, carcinogens)*
* Recombinant or synthetic DNA
* New investigational compounds or drugs
* Body fluids or tissues
* Cells, or cell lines of human or animal origin
* Antigens or antisera of human or animal origin
 | [ ]  No [ ]  Yes | Complete section ‘**C: Use of Hazardous or Potentially Hazardous Agents**’ |

| 1. USE OF ROUTINELY ADMINISTERED DRUGS, BIOLOGICS, OR OTHER COMPOUNDS
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1. **Provide the requested information outlined within the table below.**

***Note***: *A* *pharmaceutical grade (‘pharma grade’) substance is a drug, biologic, or reagent that is approved by the Food and Drug administration (FDA) for use in humans or animals or for which a chemical purity standard has been established by the United States Pharmacopeia-National Formulary (USP-NF), or British Pharmacopeia (BP).*

*In the table below, it is acceptable to provide a range for the dosage to allow flexibility in the procedure.*

| Substance Name | Purpose of Substance | Source/Supplier Name | Pharma Grade? | Dose, Route, & Administration Schedule |
| --- | --- | --- | --- | --- |
| Enter text | Enter text | Enter text | [ ]  Yes[ ]  No | Enter text |
| Enter text | Enter text | Enter text | [ ]  Yes[ ]  No | Enter text |
| Enter text | Enter text | Enter text | [ ]  Yes[ ]  No | Enter text |
| Enter text | Enter text | Enter text | [ ]  Yes[ ]  No | Enter text |
| Enter text | Enter text | Enter text | [ ]  Yes[ ]  No | Enter text |
| Enter text | Enter text | Enter text | [ ]  Yes[ ]  No | Enter text |
| Enter text | Enter text | Enter text | [ ]  Yes[ ]  No | Enter text |
| Enter text | Enter text | Enter text | [ ]  Yes[ ]  No | Enter text |
| Enter text | Enter text | Enter text | [ ]  Yes[ ]  No | Enter text |
| Enter text | Enter text | Enter text | [ ]  Yes[ ]  No | Enter text |
| Enter text | Enter text | Enter text | [ ]  Yes[ ]  No | Enter text |
| Enter text | Enter text | Enter text | [ ]  Yes[ ]  No | Enter text |
| Enter text | Enter text | Enter text | [ ]  Yes[ ]  No | Enter text |
| Enter text | Enter text | Enter text | [ ]  Yes[ ]  No | Enter text |
| Enter text | Enter text | Enter text | [ ]  Yes[ ]  No | Enter text |

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| 1. **Will this study involve the use of any routinely used drugs, biologics, or compounds that are NOT pharmaceutical grade?** [ ]  No [ ]  Yes *(answer the questions below)*
2. Provide justification for why the use of non-pharmaceutical grade material(s) is necessary:

Enter text1. If known, specify the purity, sterility, storage, date of expiration, known side effects, and adverse reactions of the non‑pharmaceutical grade substance(s) to be used in this study:

Enter text |
| 1. **Will this study involve the use of any halogenated inhalant agents such as isoflurane?**

[ ]  No [ ]  Yes *(describe the method for scavenging waste anesthetic gas below)*Enter text |
| 1. **Will this study involve the use of any controlled substances?** [ ]  No [ ]  Yes *(answer the questions below)*
2. Name(s) of controlled substance:

Enter text1. Does the principal investigator hold a valid DEA registration certificate? [ ]  Yes [ ]  No *(explain below)*

Enter text1. Record the expiration date listed on the current DEA registration certificate below:

Enter text |

| 1. USE OF HAZARDOUS OR POTENTIALLY HAZARDOUS AGENTS
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1. **Provide the requested information outlined within the table below.**

***Note***: *The use of hazardous or potentially hazardous substances 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 Office (*[*RSO*](https://www.une.edu/campus/ehs/laboratory-safety/radiation-safety)*)* ***before*** *IACUC approval can be granted.*

| Category | Contact | Name of Agent(s) | 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 |
| Other | Enter text | Enter text | Enter text | Enter text |

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| 1. Will this study involve the use of any biological agents as identified in the above table?

[ ]  No [ ]  Yes *(answer the questions below)*1. This study will be conducted at Animal Biosafety Level (ABSL): [ ]  1 [ ]  2 [ ]  3 [ ]  4

*Note: Animal biosafety levels are designed to protect personnel from exposure to potentially infectious materials. Quarantine facilities and procedures (e.g., use of a biosafety cabinet, appropriate PPE for animal care staff, etc.) must be utilized to prevent spread of infectious materials from animal to animal or persons. At present, UNE is not set up for ABSL level 3 or 4 research.* 1. Do you plan to conduct ABSL level 3 or 4 research at another location/facility?

[ ]  No [ ]  Yes *(provide the name of the facility, location, and contact person below)*Enter text |
| 1. Will this study involve the use of radioactive materials? [ ]  No [ ]  Yes *(answer the questions below)*

*Note: A laboratory SOP approved by the UNE IACUC may be referenced to describe the procedure. Please specify the SOP # and the SOP title in your description of the procedure below.* 1. Describe the method for removal of radioactive waste.

Enter text1. Describe the plan to monitor contaminated surfaces/equipment, and the method for decontamination.

Enter text |
| 1. Will this study involve the use of any biological material or human or animal products for use in rodents (e.g., cells or cell lines, antigens, antisera, etc.)? [ ]  No [ ]  Yes *(answer the questions below)*
2. Indicate the source of the material.

Enter text1. Specify if the material is sterile or attenuated.

Enter text1. Has the material been tested for pathogens? If yes, provide test facility/laboratory information.

Enter text1. Principal Investigator Attestation *(check the box below):*

[ ]  I confirm the materials to be used have not been passed through rodent species outside of the UNE vivarium, and to the best of my knowledge the materials remain uncontaminated with rodent pathogens. |
| 1. Will this study involve the use of any new investigational compounds or drugs?

*Note: A new investigational compound or drug may be produced by a laboratory or supplied by a manufacturer for testing in an experimental setting only. Chemical purity standards are generally not established yet. Therefore, new investigational compounds or drugs are considered to be non-pharmaceutical grade with no available human or veterinary pharmaceutical grade equivalent or alternative.*[ ]  No [ ]  Yes *(answer the questions below)*1. Specify the name(s) of the new investigational compound or drug.

Enter text1. Indicate the intended purpose of the new investigational compound(s) or drug(s).

Enter text1. Indicate the source(s) of the new investigational compound or drug.

Enter text1. If known, specify the purity, sterility, storage, date of expiration, known side effects, and adverse reactions of the new investigational compound(s) or drugs(s).

Enter text1. Specify the dose, route, and administration schedule of the new investigational compound(s) or drug(s).

Enter text1. Describe the plan to monitor animals exposed to the new investigational compound(s) or drug(s) to ensure animal welfare.

Enter text |
| 1. Describe the practices and procedures required for the safe handling and disposal of contaminated animals and material associated with this study.

*Note: The description of the practices and procedures should include details such as signage, notification of facility personnel, required PPE, and special animal husbandry procedures as necessary.**A laboratory SOP approved by the UNE IACUC may be referenced to describe the procedure. Please specify the SOP # and the SOP title in your description of the procedure below.* Enter text |