

 **Institutional Biosafety Committee**

**IBC Annual Continuing Review (for Non-Exempt protocols)**

**IBC Revision/Modification to Protocol\***

**IBC Study Completion Notification**

Administered by:

UNE Office of Research Integrity

Pickus 106

11 Hills Beach Road

Biddeford, ME 04005

\* ***Please see IBC protocol submission instructions for guidance in identifying when it’s appropriate to submit a revision/modification or if a new protocol submission will be required. If you need further assistance with the UNE IBC process, please contact the IBC directly at*** ***ibc@une.edu******, or via phone at 207-602-2117.***

CHECK ALL THAT APPLY:

[ ]  IBC Annual Continuing Review (for Non-Exempt Protocols)

 \* If your project was deemed Non-Exempt during initial review you are required to complete annual reviews

[ ]  IBC Revision/Modification

 \* Please be sure to submit an IACUC amendment if your IACUC protocol is effected by this change

[ ]  Study Completion

 \* You MUST notify the IBC when your study is complete

**HANDWRITTEN SUBMISSIONS WILL NOT BE ACCEPTED**

**PLEASE FILE ELECTRONICALLY**

**Section I: Background Information**

1. Title of Project:

 Protocol Number:

2. Contact Information:

Name of Principal Investigator (PI):

Phone #:

Email Address:

Campus Mailing Address:

Project Campus Location:

Name of Co-Principal Investigator (co-PI):

Phone #:

Email Address:

Campus Email Address:

Is Co-PI from outside institution? Yes [ ]  No[ ]

Project Start Date:       Project End Date:

3. Is this project funded? Yes [ ]  (list funding source below) No[ ]

**Section II: Status of IBC Protocol**

1. This study is: [ ]  Active [ ]  Completed or Discontinued
2. Please provide a brief summary of work performed under this protocol to date:

|  |
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1. Are you making any modification to your original submission?

 [ ]  Yes

 Please complete **Section III: Request for IBC Revision/Modification**

 [ ] No

Please initial box below and go to **Section IV: Signatures**

**Section III: Request for IBC Revision/Modification**

1. Is this amendment for the addition of personnel or Genetically Modified (GE) animals **ONLY**?

 [ ]  Yes\* [ ]  No

 \* Please fill in **Section 1A and/or 1B** below accordingly and skip to **Section IV:Signatures**

 **1A.** Change in personnel or personnel roles. Explain specific role(s) of new personnel in this project, describe their experience with the specific procedures to be performed and/or who will train them.

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| --- | --- | --- | --- | --- | --- |
| **Add** | **Delete** | **Name** | **CITI Training Completed** | **Specific role(s)/procedure(s)** | **Specific experience with the procedures and species and/or who will train** |
| [ ]  | [ ]  |       |       |       |       |
| [ ]  | [ ]  |       |       |       |       |
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**1B.** Change in/addition of Genetically Engineered (GE) animals. Explain genus, species, strain, vendor, phenotypic consequences and special care requirements.

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| **Genus (e.g. *Mus)*** | **Species (e.g. *musculus)*** | **Strain/****Subspecies** | **Source (name of vendor)** | **Specific phenotypic consequences of genetic manipulation** | **Special Care or Monitoring Required of Animal Care Staff** |
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1. Are you adding any of the following to your study? [ ]  Yes\* [ ] No

**If “YES” check** [ ]  Controlled Substances/Other Drugs

**all that apply:** [ ]  Radioactive Materials

 [ ] Hazardous Materials/Chemicals

 [ ] Biological Agents

 [ ]  InVivo Procedures

**CHEMICALS, MATERIALS AND ANIMAL USE**

Use of agents requires approval of a separate review committee(s) or department listed below. Please fill in any information applicable to your revision/modification.

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| --- | --- | --- | --- | --- | --- | --- | --- |
| **Please “ √” All That****Apply** | **Category****Of****Material** | **Material** | **Risk group\*****(1-4)** | **BSL\*****(1-4)** | **Approving****Committee** | **Date of****Approval** | **Protocol #:****(if applicable)** |
| [ ]  | RadioactiveMaterials |  | [ ] 1 [ ] 2[ ] 3 [ ] 4 | [ ] 1 [ ] 2[ ] 3 [ ] 4 | RSC |  |  |
| [ ]  | RecombinantDNA |  | [ ] 1 [ ] 2[ ] 3 [ ] 4 | [ ] 1 [ ] 2[ ] 3 [ ] 4 | IBC |  |  |
| [ ]  | Hazardous Materials/Chemicals |  | [ ] 1 [ ] 2[ ] 3 [ ] 4 | [ ] 1 [ ] 2[ ] 3 [ ] 4 | EH&S |  |  |
| [ ]  | Biological Agents |  | [ ] 1 [ ] 2[ ] 3 [ ] 4 | [ ] 1 [ ] 2[ ] 3 [ ] 4 | IBC |  |  |
|  | Species | ABSL level |  |
| [ ]  | InVivoAnimalWork |  | [ ] 1 [ ] 2[ ] 3 [ ] 4 | IACUC |  |  |

\* Please click [here](https://www-envirinfo.llnl.gov/content/enviroRecent/livermoreSite/BSL-3_EA_Appendix_A_Final_R1_Revised_25Jan08.pdf) to see CDC Guidance on Biosafety Level Criteria (BSL), [here](https://www.cdc.gov/biosafety/publications/bmbl5/bmbl5_sect_ii.pdf) to view CDC Biological Risk Assessment Criteria or [here](https://www.cdc.gov/biosafety/publications/bmbl5/bmbl5_sect_v.pdf) to view Veterbrate Animal Biosafety Level Criteria (ABSL).

Briefly describe, and explain the reason for the revision/modification. Please attach a copy of the original protocol, with specific changes highlighte, including any changes in the use of controlled substances, transgenic animals, and biohazards.

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Describe the practices and procedures required for the safe handling and disposal of contaminated material associated with this study in the space below.

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| Description: |
| SOP#: (if applicable SOP has been approved by the IBC committee) |
| SOP Title: |

Please provide any additional safety considerations for the use of these materials and/or animals.

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**Section IV: Signatures**

**Original or electronic signatures are required. The application will not be processed**

**until all signatures are obtained.**

**SIGNATURE OF PRINCIPAL INVESTIGATOR(S):**

**The undersigned accept(s) responsibility for the study, including adherence to any federal or state regulation; IBC policies and procedures; requirements of the granting agency (if applicable); ensuring that appropriate training is provided for all students/staff working in the laboratory; and all UNE policies regarding research conduct, safety and security. In case of student studies, the faculty supervisor and the student share responsibility for adherence to policies.**

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| **Print Name:** | **Signature:** | **Date:** |
| **Print Name:** | **Signature:** | **Date:** |
| **Print Name:** | **Signature:** | **Date:** |

**Return completed form to the IBC mailbox via e-mail at** **ibc@une.edu****. Contact Ivy Bergquist, Research Compliance Administrator, at 602-2117 if you have any questions.**