

 Institutional Biosafety Committee

BIOSAFETY APPLICATION

For the Use of Transgenic Animals ONLY

Administered by:

UNE Office of Research Integrity

Pickus 106

11 Hills Beach Road

Biddeford, ME 04005

 *If you have any questions or need assistance with the UNE IBC process, please contact the IBC directly at* *ibc@une.edu**, or via phone at 207-602-2117.*

Instructions

Please complete this application for an initial submission to the IBC if you plan on using transgenic mice, rats, and/or fish at UNE. DO NOT leave any questions blank. If you currently have an IBC protocol on file and need to make changes to that protocol or submit the required annual review, please submit the Modification/Annual Review/Completion Form.

IBC Review of Exempt Research: All research involving the purchase, import, and/or breeding genetically-modified animals in any UNE facility must submit this form to have an exemption designation on file with the IBC.

* Research qualifying for IBC Exemption status will **not require** Annual Reviews or 3-Year Renewals. However, if at any time changes are made to a research protocol as Exempted, you must submit the changes to the UNE IBC using the Significant/Minor Modification/Annual Review Form.
* All research using animals on campus MUST also submit a protocol to the UNE IACUC for approval. You will need your IBC protocol number when submitting this form.

Important Information

Training of Principal Investigators & Research Personnel:

For protocols looking to purchase, import and/or breeding of Genetically Engineered (GE) animals ONLY, the CITI training is NOT REQUIRED.

Significant & Minor Modifications: Minor modifications to Exempt research are handled at the IBC administrative level and do not require full IBC review. Common examples of minor modifications include the additional of research personnel or students and the addition of transgenic animal lines. Please contact the IBC if needed for help in determining the degree of modification you intend to make to your research.

IBC Incident Reports: *Section IV-B-7-a-(3)* of the *NIH Guidelines* requires researchers to investigate and report to the Biological Safety Officer (BSO) of the UNE Environmental Health and Safety Office and the IBC any significant problems, research-related accidents or illnesses, or violations of the *NIH Guidelines*.

Investigators: The [*NIH Guidelines*](http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines) state that the Principal Investigator of an IBC project is responsible:

* For ensuring that the laboratory staff are appropriately trained (*Section IV-B-1-h*);
* For full compliance of the conduct of the IBC research (*Section IV-B-7*); and
* For the supervision of safety performance by laboratory staff (*Section IV-B-7*).

Please note that correspondence from the IBC will be directed to the Principal Investigator as the recognized individual responsible for the research, and not to co-investigators or other lab personnel. However, a co-investigator may be listed as the alternate contact if preferred.

*If you have any questions or need assistance with the UNE IBC process, please contact the IBC directly at* *ibc@une.edu**, or via phone at 207-602-2117.*

Application Form

1) Complete and submit the application via email attachment to the IBC at ibc@une.edu.

2) Attach CITI Certificates of Completion for each individual listed on the protocol submission.

3) Provide a scanned or pdf file of the signed Assurance page with original signatures to the IBC at ibc@une.com.

NOTE: If you plan on using or collecting biological agents, samples, etc. from live vertebrate animal subjects or human subjects, or if your proposed research will involve radiation/radioactive isotopes, you will also need to seek approval from the appropriate UNE committee.

Please fill in the appropriate information if this application is being submitted in conjunction with an IACUC, IRB, or RSC application. If the application is pending, list the date submitted:

IACUC Application (animal subjects) Yes [ ]  Protocol #\*:  Date Submitted:

IRB Application (human subjects) Yes [ ]  Protocol #\*:       Date Submitted:

RSC Application (radioactive materials) Yes [ ]  Protocol #\*:       Date Submitted:

\*Please fill in N/A if no protocol # has been assigned

*NOTE: As long as an existing or pending IACUC application covers work to be performed, animals may be ordered once the UNE IBC has confirmed receipt of your IBC Application; you do not need an official approval letter prior to ordering these animals. However, you may not receive animals at the institution until you have an approval/exemption letter from both the IACUC and IBC for the work to be performed.*

Section I: Background Information

1. Title of Project:

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[ ]

4. List all personnel involved in the project and their respective roles in the research\*

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| --- | --- | --- |
| Student/ PI(s) Name, or Individuals Authorized to Conduct Procedures 🡫 | Procedure(s) to be performed  | Training received |
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*\*Please attach CITI Certificates of Completion for all investigators and personnel listed above.*

5. The proposed protocol involves (check all that apply):

 [ ]  Recombinant/Synthetic DNA

 [ ]  Infectious agents

 [ ]  Select Agents

 [ ]  Toxins

 [ ]  Human Derived Cell Lines

 [ ]  Purchasing, importing, and/or breeding of Genetically Modified (GE) animals ONLY \*

\*If you checked ANY other boxes you are filling out the WRONG form. Please see the website to retrieve the correct form.

6. This protocol review is for:

Research Project [ ]

Teaching/Course [ ]  Course #:

Student Project [ ]  Course #:

Other (please explain) [ ]

Section II: Project Description

1. Provide a 2-3 sentence abstract of the project that***specifically relates to the work*** with the genetically modified animals. If an IACUC protocol is/will be associated with this IBC protocol, be sure to summarize how the work with recombinant or synthetic nucleic acid molecules relates to the animal work, making sure to provide a detailed description of how the line is generated and the source.

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| --- | --- | --- |
| 1. Does the work involve live (living) vertebrate animals? | [ ]  Yes | [ ]  No |
| 2. Is there an IACUC application submitted or approved for this research involving recombinant or synthetic nucleic acid molecules? \*If you are not the named PI on the linked IACUC protocol, provide the name of the PI on the IACUC application.*If you need more information regarding animal research review and approval requirements, please visit the* [*UNE IACUC*](http://www.une.edu/research/compliance/iacuc) *website.* | [ ]  Yes\* | [ ]  No |
|       |
| 3. Will transgenic, knockouts, gene-targeted, or other genetically engineered animals be used? | [ ]  Yes | [ ]  No |
| 4. Does the project involve rodents (parental or offspring) that contain more than 50% of the genome of an exogenous eukaryotic virus from a single virus family? | [ ]  Yes | [ ]  No |
| 5. Will recombinant or synthetic nucleic acids or toxins be administered to live or intact animals, injection of viral vectors, transfected cells, plasmids, or the transplantation of genetically modified cells, tissues or organs into animal research subjects that fall under IACUC oversight? \*If YES, you are filling in the wrong form and should visit the IBC website to retrieve the correct form.  | [ ]  Yes\* | [ ]  No |
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Assurance Page

I agree to conduct this research in accordance with the compliance policies of the University of New England Institutional Biosafety Committee, including all requisite training of students, staff, and other professionals participating in this research.

1. I have consulted Section IV-B-7 of the [*NIH Guidelines*](http://oba.od.nih.gov/rdna/nih_guidelines_oba.html) describing the responsibilities of the Principal Investigator and hereby agree to comply fully with all provisions of the [*NIH Guidelines*](http://oba.od.nih.gov/rdna/nih_guidelines_oba.html).
2. I understand I am responsible for assuring that my research facilities are in compliance with local, state and federal environmental laws and regulations.
3. I understand that I am responsible for the proper conduct of any research by laboratory personnel that are directly related to this protocol application
4. I understand that all changes in the research protocol (including changes in the source recombinant or synthetic nucleic acids, host-vector systems, dosage ranges, laboratory room changes, etc.) or research participants must be reported to the IBC Office.
5. If funded by an extramural source, I assure that this application accurately reflects all procedures involving Recombinant or Synthetic Nucleic Acids as described in the grant proposal to the funding agency.
6. The information within this application is accurate to the best of my knowledge.
7. I understand that yearly reporting is required for continuing approved research on all non-exempt protocols.
8. I understand that all non-exempt protocols must be resubmitted for committee review after a term of three years.

It is the Principal Investigator’s responsibility to ensure that all personnel involved in this study are appropriately trained, and are provided the equipment necessary to perform at the designated biosafety containment level.

NOTE: EHS in conjunction with IBC reserves the right to conduct inspections of research facilities at any time.

Principal Investigator’s name typed:

Principal Investigator’s signature

1) Complete and submit the application via email attachment to the IBC at ibc@une.edu.

2) Submit the Investigator’s CV/biosketch via email attachment if required (required when submitting initial non-exempt protocol).

3) Attach CITI Certificates of Completion for each individual listed on the protocol submission.

4) Provide a scanned or pdf file of the signed Assurance page with original signatures to the IBC at ibc@une.com.