

 **Institutional Biosafety Committee**

**BIOSAFETY APPLICATION**

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 infectious agents, select agents, toxins, and/or recombinant DNA, a part of your research, teaching, or testing activities at UNE. DO NOT leave any questions blank in required sections. 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 recombinant or synthetic nucleic acid molecules, materials or procedures, infectious agents, toxins, or select agents must be submitted to the UNE IBC for IBC review and Exemption. IBC purview includes research in which genetically-modified animals are purchased, imported, or bred in any UNE facility.

* 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.
* Please see below for common examples of exempted research activities and instructions for completing this form (abbreviated) for the purchase, import, and /or breeding of genetically engineered animals only. If you are unsure whether or not your research qualifies for Exemption status, please contact the IBC at ibc@une.edu.
	+ Common examples of exempt research activities:
		- Manipulation of oligonucleotides that cannot replicate in any living cell and are not designed to incorporate into DNA (e.g., oligonucleotide probes or primers).
		- Recombinant nucleic acid molecules propagated in cell culture or in E. coli host-vector systems, as long as the rDNA molecules contain less than one-half of any eukaryotic viral genome, and do not include DNA from risk group 3, 4 or restricted organisms.
		- Generation or use of transgenic animals in experiments requiring only BSL1 containment.
	+ **Purchase, import and/or breeding of Genetically Engineered (GE) Animals only:**
		- **Instructions:** Complete Sections I – III and Section VIII - IX. **STOP** at Section IX, and follow the instructions on the form for submission.

**IBC Review of Non-Exempt Research**: All research involving recombinant or synthetic nucleic acid molecules, materials or procedures, infectious agents, toxins, or select agents must be submitted to the UNE IBC for IBC review and Approval.

* Research qualifying for IBC Approval status will be provided an approval term of three years which is renewable at expiration by resubmission of this form. Non-exempt research protocols also require annual review throughout the 3-year approval term. Please use the Significant/Minor Modification/Annual Review Form for submission of annual reviews.
	+ The UNE IBC will distribute *courtesy* 90-day, 60-day, and 30-day renewal notices via email prior to the 3-year expiration date. The UNE IBC will not distribute courtesy notices for required annual reviews.
	+ Investigators are responsible for updating contact information with the UNE IBC so that renewal notices are received.
* **Performance of non-exempt research without an active IBC protocol is considered serious non-compliance that will result in termination of the non-compliant research activities, and in extreme case, can result in suspension of all NIH funds for rDNA research at the University of New England.**

**Additional Considerations for Non-Exempt Research**

**Risk Assessment, Containment Determination, and Other Issues to Consider**: In determining the appropriate containment and conducting an accurate risk assessment for a project, it is important to consider the factors that may raise concerns regarding the materials or agent(s) used.

Factors used to determine the level of containment include: virulence, infectious dose, environmental stability/instability, route of spread/infection, communicability/pathogenicity, safety procedures/operations, quantity of agent(s), availability of vaccine or treatment and any gene product effects such as: toxicity, physiological activity, or allergenicity.1

Investigators should additionally consider any potential for unintended adverse events and/or any potential for misuse of the research. Special consideration should be given to any experimental paradigms that: 2

* Would confer resistance to therapeutically useful antibiotics or antiviral agents in humans, veterinary medicine, or agriculture
* Would enhance the virulence of a pathogen or render a non-pathogen virulent
* Would increase transmissibility of a pathogen
* Would alter the host range of a pathogen

1[NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)](http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines), Section II-A-3, November 2013

 2 [Dual Use Research of Concern](http://osp.od.nih.gov/office-biotechnology-activities/biosecurity/dual-use-research-concern), National Institutes of Health, Office of Science Policy

**Important Information**

**Training of Principal Investigators & Research Personnel**: All principal investigators, co-investigators, and any/all research personnel must complete the required IBC CITI training to conduct research falling within the purview of the UNE IBC prior to submission of an IBC application. All individuals must take the Biosafety Complete Training Series found [here.](https://www.citiprogram.org/)  The CITI training certification is valid for four (4) years.

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

**NOTE:** Applications received prior to the completion of the required training by all researchers/staff will be considered incomplete at time of receipt and will not be reviewed until proof of training completion is received by the IBC.

**Significant & Minor Modifications**: Minor modifications to Exempt and/or Non-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.

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**NOTE:** Significant modifications to Non-Exempt research require full IBC review and will require the investigator to submit the Significant/Minor Modification/Annual Review Form at least **7 days** prior to the next scheduled UNE IBC meeting (find meeting dates here). These include such changes as:

* Addition of a new vector system not previously approved by the IBC for use by the investigator
* Addition of new *in vivo* work not previously approved by the IBC (previous approval was for *in vitro* work only)
* Change in Biosafety Level (either upgrade or downgrade)
* Significant change in DNA inserts as noted below (see **NOTE Regarding Inserted DNA\***)
* Change of a principal or co-investigator on Non-Exempt research to an investigator who does not currently have any active IBC approvals on file – IBCs must review the investigator’s background and experience

**\*NOTE Regarding Inserted DNA**: In some instances, the investigator may not be able to determine in advance all of the inserted nucleic acid segments (or transgenes) to be used in a particular vector system. In most instances, the addition of new inserts/transgenes will not alter the biosafety level and will not require full IBC review at a convened IBC meeting. These changes can be submitted to the IBC as minor modifications on a rolling basis. However, there are exceptions that necessitate submission of a significant modification to Non-Exempt research for review by the full IBC, including, but not limited to:

* Inserting genes with oncogenic potential into any viral vector
* Manipulating genes from any HHS or USDA Select Agent or Toxin
* Manipulating genes from highly pathogenic avian, 1918 pandemic H1N1, or non-contemporaneous H2N2 influenza strains
* Inserting nucleic acid molecules that have the potential to increase the pathogenicity or virulence of a vector system
* Transferring a drug resistance trait that has the potential to compromise the use of the drug to control disease in humans and/or animals
* Transferring a herbicide or insecticide resistance trait into a crop plant
* Transgenic modification of a food animal

**Review of Non-Exempt Research**: Non-exempt research requires review and approval by a quorum - one more than half - of IBC members at a convened IBC meeting. You must submit completed IBC applications for review 2 weeks prior to the scheduled meeting date. The IBC meets monthly, and the scheduled meeting dates can be found here. Please note the scheduled meeting times and plan accordingly for the submission of an application to be reviewed prior to your anticipated start date. *(NOTE: The UNE IBC cannot guarantee review times for non-exempt research activities less than 60 days.)*

**Annual Review Reporting**: To maintain continuing IBC approval on Non-Exempt projects only, protocol update reports must be submitted annually. To simplify annual reporting, the researchers should complete only Sections x-x of the Significant/Minor Modification/Annual Review Form. Additional sections may also require completion if changes as indicated in the form instructions are proposed to the research.

* The UNE IBC will distribute *courtesy* 90-day, 60-day, and 30-day renewal notices via email prior to the annual renewal date.
* Investigators are responsible for updating their contact information with the IBC Office to assure receipt of renewal notices.

**3-Year (Full) Renewal**: To maintain the most relevant data related to research at UNE, investigators wishing to continue Non-Exempt research beyond the three-year expiration date are required to complete this entire IBC application as a “Full Renewal”.

* The UNE IBC will distribute *courtesy* 90-day, 60-day, and 30-day renewal notices via email prior to the expiration date.
* Investigators are responsible for updating their contact information with the IBC Office to assure receipt of renewal notices.

**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*.

**Expired Non-Exempt Protocols**: Protocols that are not renewed prior to their three-year expiration date will automatically expire the day following the expiration date. An official expiration letter is distributed to the investigator and other compliance offices/divisions as appropriate.

* Work on expired protocols cannot be continued or “re-started” once the expiration letter has been issued without submission of a new review application and subsequent approval.

**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) Submit the Investigator’s CV/biosketch via email attachment **if required (required for initial submission of non-exempt research).**

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.

**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\*

|  |  |  |
| --- | --- | --- |
| 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 \***(Complete Sections I – III and Section VIII – IX. **STOP** at Section IX, and follow the instructions on the form for submission)

\* CITI training is NOT required

6. This protocol review is for:

Research Project [ ]

Teaching/Course [ ]  Course #:

Student Project [ ]  Course #:

Other (please explain) [ ]

**Section II: Project Summary**

**HELPFUL HINTS for completing this section:**

* + Do *not* copy from a grant application!
	+ Limit the description(s) to the materials relevant to IBC review (recombinant or synthetic nucleic acid molecules toxins, infectious agents, select agents, etc.) of the project
	+ Address any potential biosafety issues and how they will be minimized.
	+ Use non-scientific language so that the IBC community members may understand the research project.
1. Provide a 2-3 sentence abstract of the project that***specifically relates to the work*** with the recombinant or synthetic nucleic acid molecules, toxins, select or infectious agents. 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. If transgenic mice are used, provide a detailed description of how the line is generated and the source.

1. Describe the experimental procedures and techniques to be used with the recombinant or nucleic acid molecules in the project.

 For example, if the research involves a recombinant virus, bacteria, or other organism:

* Describe the vectors and the transgenes being used
* Describe any use of toxins or infectious agents
* Describe how they are used in the research project

1. Summarize the use of all viruses, including lentiviral vectors.

D. If using multiple biosafety levels, describe the procedures to be performed at each level.

(For example: Work with plasmids at BSL-1, work with 3rd generation (4-plasmids) HIV-1 lentiviral vectors at BSL-2; vaccine study with a single HIV-1 gene at BSL-1).

E. Are you using standard precautions used for BSL2 work? [ ]  Yes [ ]  No\*

 \* If **NO**, please explain why you are not and what precautions used for BSL2 work.

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 F. Does the investigator have prior experience with the organisms (viruses, bacteria, fungal agents, etc.), vectors, or recombinant materials described in this application?

If **YES**, describe the laboratory and safety experience working with these materials and provide the number of years.

If **NO**, describe training and/or experience with relevance to biosafety in microbiological and medical laboratories.

G. Please list and/or describe all current training (beyond completion of required IBC CITI training) relevant to the proposed work that will support IBC approval of research activities with the materials described. Specifically, identify trainings such as Chemical Hygiene, BloodBorne Pathogens, general laboratory safety, relevant IACUC trainings, etc.

**Section III: Determination of Use**

Indicate all that apply by checking ALL applicable boxes.

|  |  |
| --- | --- |
| **A.** **[ ]**  | Using recombinant or synthetic nucleic acid molecules for detection purposes (e.g. GFP, YFP, PCR, ISH, radioactive nucleotides, etc.) |
| **B. [ ]**  | Creating or using genomic libraries |
| **C. [ ]**  | Cloning and vector construction in bacteria and yeasts |
| **D. [ ]**  | Expression of recombinant or synthetic nucleic acid products in cultured cells |
| **E. [ ]**  | Use of human cells/cell lines\* (E.g. HEK 293 cell lines)\*All human derived materials including cell lines are to be handled under BSL-2 precautions. |
| **F. [ ]**  | Use of animal cells/cell lines or tissues (e.g. tissue culture research) |
| **G. [ ]**  | Use of *human* stem cells or iPS cells (embryonic or adult) |
| **H. [ ]**  | Use of cloning genes from, or into, a risk group 2 agent  |
| **I. [ ]**  | Administration of recombinant or synthetic nucleic acid molecules into animals (e.g. transformed cells, vectors) |
| **J. [ ]**  | Experiments involving whole plants in research |
| **K. [ ]**  | Propagating culture volumes exceeding 10 liters at one time |
| **L. [ ]**  | The use or manipulation of infectious viruses or replication-defective viruses or viral vector(s) with helper virus |
| **M. [ ]**  | Using or cloning of toxin molecules genes (e.g. deliberate formation) |
| **N. [ ]**  | Using non-recombinant infectious agents |
| **O\*. [ ]**  | Transfer of a drug resistance trait into a risk group 2 agent |
| **P\*. [ ]**  | Transfer of a drug resistance trait into a Select Agent (see 42CFR73, 7CFR331, 9CFR121 for more information regarding select agents regulations)  |

**\*NOTE** **for boxes Q & R (if checked):** Per the [*NIH Guidelines*: Section III-A-1-a](http://oba.od.nih.gov/oba/rac/Guidelines/NIH_Guidelines.htm#_Toc351276230). The deliberate transfer of a *drug resistance trait* to a microorganism, that is not known to acquire the trait naturally, when such a manipulation could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture, is considered to be a ***Major Action*** and requires federal Recombinant Advisory Committee (RAC) review. If either box Q or R are checked, please provide the drug resistance information in the Project Summary (Section II).

**Section IV: Biosafety Level Containment & Risk Group Information**

NOTE: More than one option may apply to the research; check and indicate ALL that apply.

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| **1.** Indicate your assessment of the risk groups (or class) of ALL material(s) used in the research project (*cells to left will expand).*  |
| [ ]  | **Risk Group 1** | Agents are NOT associated with disease in healthy adult humans. |
| [ ]  | **Risk Group 2** | Agents are associated with human disease that is rarely serious for which preventative or therapeutic interventions ARE OFTEN available. |
| [ ]  | **Risk** **Group** **3** | Agents are associated with serious or lethal human disease for which preventative or therapeutic interventions MAY be available. |
| [ ]  | **Risk Group 4** | Agents are likely to cause serious or lethal human disease for which preventative or therapeutic interventions are NOT USUALLY available.  |
| **2.** Indicate ALL biosafety level(s) at which work is to be performed (*cells to left will expand).* |
| [ ]  | **BSL-1/ABSL-1** | **Low risk agents (generally risk group 1) of minimal potential hazard to laboratory personnel and the environment:*** Work is done on open bench tops; physical containment devices are usually not required
* Standard microbiological practices observed (washing hands and disinfecting contaminated surfaces upon completion of work; all liquid and solid wastes potentially contaminated with recombinant or synthetic nucleic acids are decontaminated before disposal)
* Biohazard signs should be posted
 |
| [ ]  | **BSL-2/ABSL-2** | **Moderate risk agents (generally risk group 2) of moderate potential hazard to laboratory personnel and the environment.** All of the above BSL-1 containment practices *plus the following:** Access to laboratory is restricted when experimental work is in progress
* Room MUST be certified at BSL-2 by EH&S (contact UNE EH&S or IBC if room is not yet certified)
* Personnel have specific training in handling of pathogenic agents
* Extreme precautions taken with use and disposal of contaminated sharps
* Biological safety cabinets (BSC) or other physical containment devices are used for procedures with a high potential to create aerosols or when high concentrations or large volumes of microorganisms are used
* Wastes are checmically inactivated or autoclaved before disposal from laboratory
* Biohazard signs MUST be posted
* Personal protective equipment (PPE) and entrance requirements must be met
* Spills and accidents that result in exposure to organisms containing recombinant or synthetic nucleic acid molecules are immediately reported to the IBC & EH&S.
 |

**Section V: Biosafety Risk Information**

NOTE: Protocols using BSL-2 or higher must be registered with EH&S.

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| --- | --- |
| **1.** Provide the date of your most recent lab inspection.  NOTE: If unknown, contact the Director of EH&S at 207-602-2488 or the Director of Research Integrity at 207-602-2244.  |       |
| **2.** Describe whether the agent(s) used in the course of this research may be infectious to humans (i.e. replication-competent vector vs. single-round of infection; potential for integration of vector into host chromosomes). Use of human cells or cell lines (i.e. HEK cells) required BSL-2 procedures as cells may harbor unknown infectious agents.  |       |
| **3.** Describe any procedures that may increase risk for accidental exposure to personnel via percutaneous or mucous membrane exposure routes or environmental release (e.g. use of needles, centrifugation, *in vivo* studies).  |       |
| **4.** Does the research involve any potential for airborne transmission of agents(s)? | [ ]  Yes | [ ]  No |
| **5.** Please describe the procedures, including any personnel protective equipment work practices, and/or engineering controls (such as Biological Safety Cabinet) that will be used to mitigate potential risks identified in 2-4 above.  |       |
| **6.** Describe the methods used for proper decontamination (e.g. specific disinfectant used or physical decontaminations method used) and disposal of the following (if applicable):  |       |
| a) solid waste(s): |       |
| b) liquid waste(s): |       |
| c) animal carcass(es):  |       |

**Section VI: Vectors, Hosts, & Recombinant or Synthetic Nucleic Acid Molecules Used**

If desired, insert vector map(s) at the end of the application in the Additional Materials section.

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| **1.**  List the organisms (bacteria, viruses or fungi, non-vertebrate organisms, etc.) used in the research.  NOTE: Be sure you explained the use of these organisms in Section II |       |
| **2.** List any known oncogenes or toxins that will be expressed and identify the expression system(s) used for expression.  |       |
| **3.** Does the research include any oligonucleotides used to manipulate gene function (e.g. siRNA, shRNA, etc.) \*If NO, skip to Question 6. | [ ]  Yes | [ ]  No\* |
| **4.** What genes wil be expressed or targeted for altered expression (e.g. knockdown)? |       |
| **5.** What type of vector is used with the oligonucleotides? |       |
| **6.** Is there any potential for increased virulence by manipulation of any of the nucleic acid molecules or genes listed above with respect to the vector or organism? \*If NO, skip to Question 8.  | [ ]  Yes | [ ]  No\* |
| **7.** Explain the details regarding the potential for increased virulence and provide the steps that will be taken to mitigate the risk involved with the increased virulence.  |       |
| **8.** List all cell lines or eukaryotic cells *including commercially available* human cell lines (e.g. CHO, COS, or HEK 293 cells) to be used in the research. State the species of origin for each of the cell lines used.* If no cells are used, state NONE.
 |       |

**Section VII: Biosafety Information: Use of Viral Vectors**

NOTE: If this section is not applicable to your research, state NONE in 1A and continue to Section VIII.

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| **1.** List viruses and/or viral vectors used in this research project. If more than one virus or viral vector is used, please number and organize the responses accordingly across the three boxes (examples follows below): |
| **A.** Specify the **virus family and/or subfamily** – please be specific for strains. Example:1. Herpesvirus: HHV-8
2. Adenovirus: Ad-14
3. Bacteriophage
 | **B.** Identify the **species of origin** **or preferred host** for each virus or vector Example:1. human
2. human
3. bacterial
 | **C.** Identify whether the virus is a **recombinant and/or wild type strain** for each one listed  Example:1. wild type
2. recombinant
3. recombinant, etc.
 |
|       |       |       |
| **2.** Does the project involve the use of Lentivirus or Lentiviral vectors?  \*If YES, Supplementary Form for Use of Lentivirus (last page of this form) must also be completed. | [ ]  Yes\* | [ ]  No |
| **3.** List inserted nucleic acids used in this proposal including both the species and the gene product: NOTE: If no inserts are used, state NONE. | **(A) Species**List the species from which the insert is derived. | **(B) Gene Product**List the gene product that is to be expressed. |
|       |       |
| **4.** Is there any potential for increased virulence with insertion of the nucleic acid molecules listed above into the vector or organism? (e.g. oncogenic or toxic transgenes or transfer of bacterial resistance) \*If NO, skip to Question 6.  | [ ]  Yes | [ ]  No\* |
| **5.** Describe the potential of this research for increased virulence and what steps will be taken to mitigate the risks of transmission.  NOTE: Virulence may be increased by changing existing sequences without introduction of new sequences (i.e. mutations in viral genes “mutants”) |       |
| **6.**  Is the virus or viral vector able to *enter or infect human cells* including cell lines, such as HEK 293 cells?  | [ ]  Yes | [ ]  No |
| **7.** Is the virus/viral vector replication-defective (replication incompetent)?  | [ ]  Yes | [ ]  No |
| **8.** Is the biosafety level of any replication-defective virus described in this application different from the generally accepted BSL for work with the type of wild virus? | [ ]  Yes | [ ]  No |

**Section VIII: Facilities, Safety, & Equipment**

|  |
| --- |
| **1.** Provide facilities information for ALL locations, including the facility used for work with animals or cell culture, as applicable to your research. * Provide the procedures to be performed in each location (e.g. cell transfections, propagation of plasmids, administration of viral vector into animals, animal housing, etc.)
* Provide the EH&S approved biosafety level of the locations (NOT the procedural biosafety level)

 \*Work at the BSL2 level or higher requires the approval of EH & S. |
|  | **Location #1** | **Location #2** | **Location #3** |
| **Building & Room #** |  |       |       |
| **Describe procedures for this location** |  |       |       |
| **Provide approved biosafety level** |  |       |       |

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| **2.** Please check all of the personal protective clothing & equipment to be used by personnel in the above facilities:  |
| [ ]  Eye/face protection [ ]  Head cover[ ]  Show covers[ ]  Gloves[ ]  Double gloves | [ ]  Lab coat[ ]  Tyveks/disposable gowns[ ]  Surgical scrubs[ ]  Automatic pipettors [ ]  Safety centrifuge/blender/grinder | [ ]  N95 particulate respirator\*[ ]  PAPR (HEPA) respirator\*[ ]  Other (please indicate):       |

\* Use of respirators requires fit testing through EH&S. Please contact them to schedule an appointment.

**Section IX: Animal Use Information: Part I**

NOTE: If you are obtaining cells or tissues from live vertebrate animals under an IACUC protocol, or plan on administering recombinant nucleic acid molecules/materials to animals (including cells from other genetically modified animals, or transformed cells), you MUST complete this section.

|  |  |  |
| --- | --- | --- |
| **1.** Does the work involve live (living) vertebrate animals? \*If NO, skip to Section XI. | [ ]  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? \*If NO, go to question 7. | [ ]  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, continue to Section X.  | [ ]  Yes\* | [ ]  No |
|  |  |  |

**Section X: Animal Use Information: Part II**

Complete this section for administration of recombinant or synthetic nucleic acid molecules, toxins, or xenotransplants into live animal subjects.

|  |  |
| --- | --- |
| **1.** What are the target cells/tissues/organs for the recombinant/synthetic genetic material or toxin? |       |
| **2.** List ALL recombinant/synthetic nucleic acid molecules or materials to be administered to animals.* Include both transformed or infected cells and any vectors (viral or non-viral)
* For cells, identify the vector(s) used to modify the cells prior to administration.
 |       |
| **3.** Do you anticipate that work with the live animal subjects will be conducted at a different BSL than the *in vitro* or wet bench portions of the study? \*If YES, please explain the necessity for different containment requirements.  | [ ]  Yes\* | [ ]  No |
|       |
| **4.** Provide the animal species (and strain) receiving the experimental agents, being sure to list each species to be used. |       |
| **5.** Describe the route of administration for each experimental agent used *in vitro* and per species (as applicable).  |       |
| **6.**  Provide the concentration and volume for each recombinant or synthetic nucleic acid molecule to be administered per species*.*  |       |
| **7.** Describe ANY risks associated w/animal husbandry related to shedding of agents/toxins and safety precautions necessary to mitigate risks. |       |

**Section XI: Use of Human Tissues**

Please visit the [UNE IRB](http://www.une.edu/research/compliance/irb) website for additional information regarding ethical human subjects research and requirements.

NOTE: All human derived materials including cell lines must be handled under BSL-2 precautions.

|  |  |  |
| --- | --- | --- |
| **1.** Does work involve human subjects, unfixed human tissues or primary human cell cultures that are obtained directly from human participants?  NOTE: Cell lines available commercially (e.g. from a cell bank such as ATCC) do not qualify as primary cells, as they are generally immortalized).  \*If NO, skip to the Additional Materials section below.  | [ ]  YesEH&S maintains oversight of human tissue use. | [ ]  No\* |
| **2.** Has an IRB application been submitted and/or approved? \*If YES, please provide the IRB protocol #: | [ ]  Yes\* | [ ]  No |
|       |

**Additional Materials**

Please attach any additional materials below as required or as desired. For example, restriction map(s), host-vector diagrams, CITI training certificates, CV’s, data or informational reference materials in support of a lower BSL, detailed preparatory information that does not fit in the application above, etc. These materials will be reviewed by the IBC and will become part of the record for this research. **Please include a bulleted list of additional attachments below.**

|  |
| --- |
|       |

**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****.**

For IBC Office use only:

|  |  |  |
| --- | --- | --- |
| Date:  | Protocol Number:  | Revision:  |

**SUPPLEMENTARY FORM FOR USE OF LENTIVIRUS**

|  |
| --- |
| **Use of manipulation of Lentivirus or Lentiviral Vectors**(If your work does **NOT** use lentiviruses or lentiviral vectors, you do not need this form for your research submission.)**NOTE:** It is not required that vectors generated with 4-plasmid lentivirus systems (3rd generation vectors) be tested for replication-competant virus. However, 3-plasmid vector lentivirus systems (2nd generation vectors) must be shown to be free of replicating virus approved at BSL-2 (for example, you must provide data or the results of a RCV assay). |
| **1.** List the specific lentiviral strain and species of origin (e.g. HIV-human; FIV-feline; SIV-simian).  |       |
| **2.** Is the lentivirus/lentiviral vector generated/produced in your laboratory at the University of New England? | [ ]  Yes | [ ]  No |
| * **3.** Provide the name(s) of the source of the lentivirus or letiviral vector(s). (The company name or investigator name(s) and/or institution(s).)
 |       |
| **4.** Is the lentiviral vector produced from a multi-component system? (e.g. separate plasmids for packaging, envelope and gene transfer) | [ ]  Yes | [ ]  No |
| **5.** Has the replication-defective vector been tested for replication—competent virus (RCV)?* Please describe the safety features of each different lentivirus or lentiviral vector system that is used in this research.
 | [ ]  Yes | [ ]  No |
|       |
| **6.** Please state the expected volume of vector to be produced or received for each lentivirus or lentiviral vector. |       |
| **7.** Please list the transgenes used (the genes inserted) in each lentivirus or lentiviral vector.* If no transgenes are used or inserted, state NONE.
 |       |
| **8.** Will lentiviruses be used to generate stable cell lines? | [ ]  Yes | [ ]  No |
| **9.** Provide the number of passages of the transduced cell lines prior to experimental use (e.g. administration into in vivo models) |       |