**Contact e-mail**: [Email]

**Title of Project**: [Project Title]

**IMPORTANT NOTE:** Combine your completed application and all supporting documents into a single file and submit it by [**clicking here**](https://forms.office.com/r/78PB7VNUqk). Submissions received after [Expiration Date] may experience delays in review. As a reminder, it is Marian University policy that no work can begin until approved by the IBC.

**Institutional Biosafety Committee Protocol Submission Form**

* All research protocols at Marian University involving Recombinant DNA must be submitted to the Institutional Biosafety Committee (IBC) for review\*.
* For purposes of the IBC, Recombinant DNA molecules include (i) molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or (ii) molecules that result from the replication of those described in (i) above.
  + Synthetic DNA segments which are likely to yield a potentially harmful polynucleotide or polypeptide (e.g., a toxin or a pharmacologically active agent) are considered as equivalent to their natural DNA counterpart.
  + If the synthetic DNA segment is not expressed in vivo as a biologically active polynucleotide or polypeptide product, it is exempt from the NIH Guidelines.
  + Genomic DNA of plants and bacteria that have acquired a transposable element, even if the latter was donated from a recombinant vector no longer present, are not subject to the NIH Guidelines unless the transposon itself contains recombinant DNA.
* A protocol submission to the IBC includes the original of this form, typed and completed in full. If items are not applicable, note N/A. The form must be signed in section XV by the investigator.
* Questions regarding completion of this form may be directed to the IBC Chair at [IBC@marian.edu](mailto:IBC@marian.edu).
* If unregistered biohazards are part of a project being proposed for external funding, this form should be submitted to the IBC at the same time as your grant proposal or as soon as possible thereafter so that the funding agency can be informed of approval in a timely fashion.
* When any revision to an approved research protocol is desired, an amendment must be filed with the IBC and approved prior to implementation. The amendment can be in the form of a memorandum indicating the changes/modifications to the research protocol and any additional information to facilitate approval.

\*Note: No applicable research shall begin prior to receiving full protocol approval by the Marian University IBC.

**Sec. I-D. Other Compliance Committee Approvals**

Animal Research (IACUC):

Currently approved protocol(s): [# ]  
Date(s) of expiration: [DATE]

PI(s) of Record: [NAME]

Pending protocol(s): [# ]

Date(s) of submission: [DATE]

PI(s) of Record: [NAME]

*\* Note: IACUC approval must be granted prior to initiation of any vertebrate animal research\**

Human Subjects Research (IRB):

Currently approved protocol(s): [# ]  
Date(s) of expiration: [DATE] or  No expiration

PI(s) of Record: [NAME]

Pending protocol(s): [# ]

Date(s) of submission: [DATE]

PI(s) of Record: [NAME]

Veterans Affairs (VA) Research (*If the research involves VA time, property, materials, or money, please complete this section.  The research must also be reviewed by the VA SRS and R&D.):*

Currently approved protocol(s): [# ]  
Date(s) of expiration: [DATE]

PI(s) of Record: [NAME]

Pending protocol(s): [# ]

Date(s) of submission: [DATE]

PI(s) of Record: [NAME]

**Sec. I-E. Funding (please list only those grants that support work covered on this protocol)**

Internal Funding

External Funding: Agency:

Grant Number:

VA Funding:

Grant Number:

**Sec. I-F. Investigators (List ALL personnel involved in this project)**

**The IDC will utilize the names you provide in this table to verify CITI training records.**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | | ***IBC USE ONLY*** | | | | | | | | | | | | |
| ***Last Name, First Name  <E-mail Address>*** | | ***Title/Job Description*** | |  | | ***Biosafety Basics*** | | ***Lab Chem Safety*** | | ***OSHA BBP*** | | ***rDNA Research*** | | ***Animal Biosafety*** | ***Other*** |
| ***Example:***  Doe, Jane <[jdoe@marian.edu](mailto:jdoe@marian.edu)> | Associate Professor / PI / Performs all experiments, Oversees Lab | | **Required:**  **Complete:** | |  | |  | |  | |  | |  | |  |
|  |  | | **Required:**  **Complete:** | |  | |  | |  | |  | |  | |  |
|  |  | | **Required:**  **Complete:** | |  | |  | |  | |  | |  | |  |

*\*Note: To add additional lines to the table, please click the “+” sign on the left hand side of the last row. \**

**Investigator Acknowledgement:** By checking this box, the PI is ensuring that all personnel listed on this protocol have access to the protocol, read it, agree to participate in said research activities, and will complete all necessary training requirements.

**Sec. I-G. Research Location(s)** Please list the building, room numbers, research activities performed in that space, and the highest biosafety level for that space and research activity. Please specify where all biological material is being used or stored.

|  |  |  |  |
| --- | --- | --- | --- |
| ***Building*** | ***Room #*** | ***Research Activities Performed*** | ***Biosafety Level*** |
| ***Example*:**  MH | MH151 | Transformation; plate assays | BL-1 |
| ***Example*:**  MH | MH151A | Cell Culture | BL-2 |
|  |  |  |  |
|  |  |  |  |

\**Note: Please include Core Facility locations in the table.*

*\*Note: To add additional lines to the table, please click the “+” sign on the left hand side of the last row.\**

**Section III-B. Recombinant DNA (rDNA) and Synthetic Nucleic Acid Molecule Information**

**Check this box if no recombinant DNA (rDNA) and/or synthetic nucleic acid are being used and proceed to Section IV.**

In the table below, please provide the original source of inserted DNA, the vector(s) (recombinant viruses), used to insert into the host, all hosts, including intermediate, in which it will be inserted, and the gene or transcription product to follow. Also, if the gene or transcription product is known to be harmful (e.g. oncogenic, toxic, mutated gene), please provide details. Any viruses included in this table should also be included in Section IV: Viral Vectors. Please list only recombinant DNAs or synthetic nucleic acids in this table.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| ***Source Species of inserted DNA*** | ***Plasmid and/or Vector(s)*** *(recombinant viruses)* ***to be used*** | ***Host(s) to be used***  *(Please include all intermediate hosts)*  ***E.g.: human cells, mouse cells*** | ***What is the gene or transcription product*** | ***Is it known to be harmful*** *(e.g. Oncogenic, Toxic, Mutated Gene)* ***to researcher or environment?***  ***If yes, please describe:*** |
| **Example:**  Human | pcDNA3.1 | E. coli, drosophila cells | RalGDS1 | No |
| Human | pcDNA3.1 | E.coli, human calls | PI3K | Yes; PIK3CA is a known oncogene |
|  |  |  |  |  |

*\*Note: To add additional lines to the table, please click the “+” sign on the left-hand side of the last row. \**

**Section IV. Viral Vectors (recombinant viruses)**

**IV-A. Adeno Associated Viral Vectors**

**Check this box if no Adeno Associated Viral (AAV) Vectors are being used.**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| ***List all AAV vectors***\**Note****:*** *AAV/rAAV work is initially assessed at BL2/ABL2. If specific project details are provided and meet certain requirements, the IBC may adjust PPE and containment requirements. Please see the supplemental document for detailed information.* | ***Promoter and encoded gene*** | ***Is encoded gene tumorigenic, a toxin, or neither?*** | ***Made with helper virus or helper plasmid?*** | ***Produced in human or insect cells?*** | ***If produced in human cells has it been purified (yes, no, or N/A)?*** | ***Source of virus? (Commercial lab, state lab, company or Made in Lab)*** |
| **Example:**  pAAV EF1 alpha | EF1-NMNAT2 | Neither | Helper Plasmid | Human | Yes | Penn Virus Core |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

*\*Note: Click the “+” sign on the left-hand side of the last row to add additional lines to the table. \**

**IV-B. Lentiviral Vectors**

**Check this box if no Lentiviral Vectors are being used.**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| ***List all Lentiviral vectors*** *(include plasmid to be packaged [shuttle plasmid])* | ***2nd, 3rd, or 4th generation?*** | ***If 2nd generation, please provide the plasmid map information as an addendum to this protocol.***  ***Also, list the packaging plasmids used.*** | ***If 2nd generation, please describe tests to confirm replication incompetence.*** *\*Note: certificates of analysis may be subject to audit and therefore must be retained by lab. \** | ***Is encoded gene tumorigenic, a toxin, or neither?*** | ***Is TAT encoded on any system component?***  ***If yes, please describe*** | ***Source of viral particle***  *(Where are the viral particles produced?)* | ***Will you use >10 liters of culture in one container?***  ***If yes, please see*** [**Appendix K of the NIH Guidelines**](https://osp.od.nih.gov/biotechnology/nih-guidelines/) |
| **Example:**  pLenti-C-Myc-DDK | 2nd | Map attached, psPAX2 | Serial passage followed by p24 ELISA | Tumorigenic | No | System Biosciences | No |
|  |  |  |  |  |  |  |  |
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*\*Note: Click the “+” sign on the left-hand side of the last row to add additional lines to the table. \**

**IV-C. Non-AAV, Non-Lentiviral Vectors**

**Check this box if no Non-AAV or Non-Lentiviral Vectors are being used.**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| ***List all Non-AAV, Non-Lenti viral vectors.*** | ***Describe tests to confirm replication incompetence.*** | ***Are you using any helper viruses or packaging/producer cell lines? Please describe.*** | ***List any essential genes that have been deleted, added, or modified from the vector/packaging system.*** | ***Is encoded gene tumorigenic, a toxin, or neither?*** | ***Does the viral vector have an expanded host range or increase tissue tropism compared to wild-type virus?*** *(i.e.: product now potentially infectious in other organisms/cells not normally infected)****?*** | ***Source of viral particles***  *(Where are the particles produced?)*  ***If you amplify or produce your own viral particle stock, please indicate “produced in your lab.”*** | ***Will you use >10 liters of culture in one container?***  ***If yes, please see*** [***Appendix K of the NIH Guidelines***](https://osp.od.nih.gov/biotechnology/nih-guidelines/) |
| **Example:**  pSIREN-RetroQ  (Clontech) | Extended S+/L- assay with PG4 cell line (Chen et al, Virology 2001) | Packaging cell line- Phoenix- ECO HEK 293T cells | Deletion in 3’-LTR enhancer | Neither | No | Produced in Lab | No |
|  |  |  |  |  |  |  |  |
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*\*Note: Click the “+” sign on the left-hand side of the last row to add additional lines to the table. \**

**Section V. Biological Materials and Toxins**

**Check this box if no biological materials are being used.**

**Sec. V-A. Biological Materials Table**

*\*Note: All hosts cells/cell lines, tissues, blood or other bloodborne pathogen material\*, microorganisms, bacteria, and viral vector particles, should also be included here. \**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | | | | | | ***Potential Routes of Transmission***  *(Mark [X] all applicable routes)*  *\*RG2 and higher* | | | |
| ***Biological Material*** | ***Source*** | ***Infectious Host Range***  ***\*RG2 and higher*** | ***Zoonotic? (Yes/No)*** | ***Risk Group (RG)*** | ***Containment Level/Biosafety Level (BL)*** | ***Injection\**** | ***Ingestion\**** | ***Inhalation\**** | ***Direct contact open wound or mucous membranes\**** |
| **Example**:  Human Cells | ATCC | Humans | Yes | RG2 | BL-2 | X |  |  | X |
|  |  |  |  |  |  |  |  |  |  |
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*\*Note: Click the “+” sign on the left-hand side of the last row to add additional lines to the table. \**

***\*****Note:**Work with human or primate cell lines is considered RG2/BL2 and requires annual Bloodborne Pathogen training. \**

*\*Note: RG1 agents can be infectious to immunocompromised individuals or cause allergic reactions. \**

1. **Should exposure occur,** list all the potential risks associated with exposure. In the event of any exposure: Monitor for symptoms, report all exposures to the Principal Investigator, and seek medical evaluation.

***Example:*** *Human cells, Human Blood/Blood Products, and Human Fluids – Potential risks of exposure include unknown bloodborne pathogens.*

|  |
| --- |
| **Begin Here:** |

**2. Are you using Biological Toxins?**

**No**

**Yes; answer all questions below:**

LD50 of biological toxin**:**

Symptoms of exposure to toxin (List):

Toxin inactivation procedures:

Total amount of any non-Select Agent toxin:

Engineering device used for reconstituting toxin:

Chemical Fume Hood\*  Biosafety Cabinet

Engineering device used for administering toxin to animals:

Chemical Fume Hood\*  Biosafety Cabinet

\* Check Chemical Fume Hood only if hood is being used for biological work.

**3. Are you using Transactive or Infectious Proteins (e.g. Prion Proteins)?**

**No**

**Yes; check all that apply below:**

Protein**:**

Agent:

Cellular Target:

Hazards of Exposure:

**Sec. V-B. Risk Group 2 and Higher Material**

*\*Note: Human cells and/or tissues and viral vectors do not need to be included in this table. \**

**Check this box if no Risk Group 2 material, other than human materials or viral vectors are being used.**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| ***Biological Material:*** | ***Infectious dose (if known), conditions ID50 determined, and citation*** | ***Highest Volume and Concentration Used at Any Time*** | ***Route of transmission for ID50*** | ***High-risk aerosol-generating procedures***  ***For each, indicate the maximum volume and concentration of material being used*** | | | |
| Sonication | Centrifugation | Large culture growth (>1 L) | Other (*e.g.*, vortexing, homogenizing) |
| ***Example:***  *V. cholerae* | 108 colony forming units (cfu) | 109 cfu  1L | Ingestion, wound exposure, inoculation | 1 ml culture  106 cfu/ml | 500 ml  108 cfu/ml | Not applicable | Vortexing: 5 ml culture, 109 cfu |
|  |  |  |  |  |  |  |  |
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*\*Note: Click the “+” sign on the left-hand side of the last row to add additional lines to the table. \**

**2. Will you deviate from standard containment and decontamination practices listed in section XI after each procedure?**

**No; Skip to Section VI.**

**Yes; please describe the proposed modified containment and decontamination practices you intend to use**:

**Section VI. Potential** [**Dual Use**](http://osp.od.nih.gov/office-biotechnology-activities/biosecurity/dual-use-research-concern)

**Check this box if none of the agents in question 1, or any other non-attenuated agent or toxin, are being used and proceed to Section VII.**

1. **Please check any of the nonattenuated agents or toxins that will be used in this protocol:**

**Avian influenza virus (highly pathogenic)**

**Bacillus anthracis**

**Botulinum neurotoxin**

**Burkholderia mallei**

**Burkholderia pseudomallei**

**Ebola virus**

**Foot-and-mouth disease virus**

**Francisella tularensis**

**Marburg virus**

**Reconstructed 1918 influenza virus**

**Rinderpest virus**

**Toxin-producing strains of Clostridium botulinum**

**Variola major virus**

**Variola minor virus**

**Yersinia pestis**

**Other:**

1. **Will your research enhance the harmful consequences of the agent or toxin?**

**No**

**Yes;** please describe and provide a risk mitigation plan:

1. **Will your research disrupt immunity or the effectiveness of an immunization against the agent or toxin without clinical and/or agricultural justification?**

**No**

**Yes;** please describe and provide a risk mitigation plan:

1. **Will your research add resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitates their ability to evade detection methodologies?**

**No**

**Yes;** please describe and provide a risk mitigation plan:

1. **Will your research increase the stability, transmissibility, or the ability to disseminate the agent or toxin?**

**No**

**Yes;** please describe and provide a risk mitigation plan:

1. **Will your research alter the host range or tropism of the agent or toxin?**

**No**

**Yes;** please describe and provide a risk mitigation plan:

1. **Will your research enhance susceptibility of a host population to the agent or toxin?**

**No**

**Yes;** please describe and provide a risk mitigation plan:

1. **Will your research generate or reconstitute an eradicated or extinct agent or toxin listed above?**

**No**

**Yes;** please describe and provide a risk mitigation plan:

1. **If you answered yes to any of the questions above, have you completed the required DURC training?**

**No. Please complete the required DURC training.**

**Yes;** please describe and provide a risk mitigation plan:

**Section VII. Select Agents and Toxins**

**Check this box if no select agents and/or toxins are being used and proceed to Section VIII.**

**1. For any select agents and/or toxins being used in this protocol, please list and contact the Biosafety Office:**

*\*Note: Reference* [*CDC*](https://www.selectagents.gov/PermissibleToxinAmounts.html) *- National Select Agent Registry for a list of permissible toxin amounts.\**

*\*Note:* [*Reference 42 CR 73 Possession, Use, and Transfer of Select Agents and Toxins; Final Rule for a comprehensive list of select agents and toxins*](http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=8a4be60456973b5ec6bef5dfeaffd49a&r=PART&n=42y1.0.1.6.61)*.\**

**2. Please list the largest amount of exempt select agent toxin investigator will have in their possession at any given time:**

**3. Will this protocol be identifying any select agents and/or toxins in humans, soil, or the environment?**

**No**

**Yes;** pleaseprovide a list of potential select agents, description of sample source(s)**:**

**Section VIII. Human Gene Transfer (HGT)**

**Check this box if no transfer of recombinant DNA or synthetic nucleic acid molecules into one or more human research participants is occurring in this protocol and proceed to Section IX.**

1. **Is this the initial clinical trial site?**

**No; has the initial site registered with NIH OSP?**

**No**

**Yes**

**Yes**

1. **Does this research have an investigator brochure?**

**No**. Without the investigator brochure, the submission is incomplete and cannot be reviewed.

**Yes; please attach brochure to this application:**

**3. Does this research have an informed consent?**

**No**. Without an informed consent, the submission is incomplete and cannot be reviewed.

**Yes; please attach consent form to this application:**

**4. What pharmacy will be used for storage purposes?**

**Name:**

**Address:**

**Containment level(s):**

**\****Note: Disposal of waste, including bandages, from humans must be described in Section XIII.\**

**Section IX. Use of Whole Animals\* in Research**

**Check here and proceed to Section X if no animals are being used in this research project.**

*\*Note: For IBC purposes, “animals” includes any organism in the kingdom Animalia.\**

**1. Please list all animal species (vertebrates, invertebrates, genetically modified, or non-genetically modified).**

**(*Example*: Transgenic Mice; Wild Type Rats; Transgenic Zebrafish)**

\*Note: Invertebrates do not require an IACUC protocol. All vertebrates DO require an IACUC protocol.\*

**2. Are any biological materials used in research with animals? Please make sure to include all materials listed in Section V, if being used with animals.**

**No**.

**Yes; check all that apply below and describe each selection in detail in Section II and Section V above:**

**This protocol involves the use of wild-type or attenuated microbial pathogens in animals.**

**This protocol involves the use of xenografts.**

**This protocol involves the use of transfected or transduced cells inoculated into animals.**

**Other; please describe:**

**3. What is the route of administration (E.g.: IV) and how will materials be administered (*e.g*., microinjection pump)?**

**4. What containment is utilized while administering materials? (check all that apply)**

**Biosafety Cabinet**

**N95 Respirator**

**Other; please complete question 5.**

**5. Please include the following (if other was marked in question 4):**

**Material volume:**

**Concentration:**

**Pressure of injection, if known:**

**Total number of injections at one time:**

**6. Are any recombinant or synthetic nucleic acid molecules used in research with animals?**

**No**.

**Yes; check all that apply below and describe each selection in detail in Section II and Section V above:**

**This protocol involves the direct administration of nucleic acids or viral or plasmid vectors to animals.**

**Other; please describe:**

**Sec. IX-A. Genetically Modified Mammalian and/or Avian Animals**

**1. Will genetically modified rodents be used in this research project?**

**No.**

**Yes; Complete table in question 4 only if new germline strains are created by methods other than breeding or if lines are biohazardous.**

**2. Will non-rodent, genetically modified, mammalian/avian animals be used in this research project?**

**No.**

**Yes; Complete table in question 4 only if new germline strains are created or if lines are biohazardous.**

**3. Are genetically modified rodents produced with the assistance of an external Transgenic Core Facility?**

**No**.

**Yes, the following method(s) will be used to make the transgenic animals:**

**Microinjection of gene into fertilized oocytes**

**Insertion of gene(s) into embryonic stem cells microinjected into oocytes**

**Use of vectors to transfect oocytes**

**Other method(s), please include description:**

*\* Note: Also complete the* [*Transgenic Core Registration Form*](http://researchcompliance.iu.edu/ibc/protocol_sub_forms.html)*.\**

**4. Genetically modified, Mammalian/Avian Table: Please complete if you are using any non-rodent genetically modified mammalian/avian animal or if you are creating genetically modified rodents in your lab by means other than breeding. Please include any mice being created via an external Transgenic Core Facility. Add any animals that are purchased/bred that are expressing a hazardous biological agent (*i.e.* whole toxin or virus).**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| ***Animal***  ***Species*** | ***How your lab refers to this strain\**** *\*Note: Must match the name used in your IACUC protocol.\** | ***Original Source of Animal\****  *\*Note: Please provide vendor number if applicable. If animals being maintained in your lab, please include the original source.\** | ***Knockout*** *(KO)****, Knock-In*** *(KI)****, Transgene*** *(T)* | ***Gene Modified*** *(genes added or removed)* | ***Potential Hazard(s)?  Please list.***  ***(human/animal)*** | ***Biological Source of Gene*** |
| ***Example*:**  Swine | B2Microglobulin | Hardin’s Farm | KO/KI | B2 Microglobulin | n/a | Human |
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**Sec. IX-B. Genetically Modified, Non-Mammalian/Non-Avian Animals**

**1. Are genetically modified, non-mammalian/non-avian Animals being used?**

**No. Please proceed to Section X.**

**Yes; please describe in Section II.**

**2. Are the genetically modified, non-mammalian/non-avian animals used in this project known to be harmful (e.g. Oncogenic, Toxic) to the researcher and/or the environment?**

**No**.

**Yes; please describe hazard(s) in detail in Section II above.**

**3. How will the non-mammalian/non-avian animals be used?**

**4**. **For insect work, what measures are being taken to ensure that animals are not being released?**

**Section X. Recombinant or Synthetic Nucleic Acid Molecules in Plants**

**Check here and proceed to Section XI if no plants or arthropods associated with plant disease are being used in this research project.**

**1. Please list all plant species used in your research:**

**2. Please check all types of experiments that apply**

**BL1-P experiments:**

Planned experiments use recombinant or synthetic nucleic acid molecule-modified plants that are not noxious weeds or that cannot interbreed with noxious weeds in the immediate geographic area

Planned experiments use whole plants and recombinant or synthetic nucleic acid molecule-modified non-exotic microorganisms that have no recognized potential for rapid and widespread dissemination or for serious detrimental impact on managed or natural ecosystems (e.g., *Rhizobium* spp. and *Agrobacterium* spp.)

**BL2-P experiments:**

Planned experiments use plants modified by recombinant or synthetic nucleic acid molecules that are noxious weeds or can interbreed with noxious weeds in the immediate geographic area.

Planned experiments use plants in which the introduced DNA represents the complete genome of a non-exotic infectious agent.

Planned experiments use plants associated with recombinant or synthetic nucleic acid molecule- modified non-exotic microorganisms that have a recognized potential for serious detrimental impact on managed or natural ecosystems.

Planned experiments use plants associated with recombinant or synthetic nucleic acid molecule-modified exotic microorganisms that have no recognized potential for serious detrimental impact on managed or natural ecosystems.

Planned experiments use recombinant or synthetic nucleic acid molecule-modified arthropods or small animals associated with plants, or with arthropods or small animals with recombinant or synthetic nucleic acid molecule-modified microorganisms associated with them if the recombinant or synthetic nucleic acid molecule-modified microorganisms have no recognized potential for serious detrimental impact on managed or natural ecosystems.

**BL3-P experiments:**

Planned experiments use exotic infectious agent with recognized potential for serious detrimental impact on managed or natural ecosystems.

Planned experiments use cloned genomes of readily transmissible exotic infectious agents with recognized potential for serious detrimental effects on managed or natural ecosystems in which there exists the possibility of reconstituting the complete and functional genome of the infectious agent by genomic complementation *in planta.*

Planned experiments use microbial pathogens of insects or small animals associated with plants if the recombinant or synthetic nucleic acid molecule-modified organism has a recognized potential for serious detrimental impact on managed or natural ecosystems.

**Section XI. Biosafety Level/Containment Selection**

**Sec. XI-A. Please check the highest appropriate physical containment level for the proposed research.**

Biohazards or recombinant DNA:  BL-1  BL-2  BL-3

Animal Research:  ABL-1  ABL-2  ABL-3

**Please check all that apply:**

Lentiviral vector Containment:

BL-1/ABL-1: Lentivirus transduced mouse cell that will be injected into animals

BL-2: Cell culture work, no delivery into animals

BL-2/ABL-2: Injection of lentiviral vector directly into an animal. Animal housing may drop to ABL-1 after 72 hours.

BL-2/ABL-2: Injection of lentiviral vector-transduced human cells into animals or injected lentiviral vector into animals engrafted with human cells.

**Please check all that apply:**

Adeno-associated vector containment:

BL-2: Cell culture work, no delivery into animals

BL-2/ABL-2: injection of AAV, containing toxic or oncogenic inserts, into animals. All work will remain at BL-2/ABL-2. Please list the specific AAVs requiring ABL-2 housing:

BL -2/ABL-2: injection of AAV, **not** containing toxic or oncogenic inserts, into animals. Animal housing may drop to ABL-1 after 72 hours. Necropsy and postmortem tissue handling of animals receiving direct injection of AAV vectors (as described above) can be performed under BL1 conditions 72 hours after final injection.

BL-2/ABL-1: injection of AAV, not containing toxic or oncogenic inserts, into animals. The IBC will consider lowering the biosafety level for animal housing to ABL-1 on a case-by-case basis based on the following criteria:

1. The nature of the transgene expression: Transgenes expressing oncogenic protein or toxin require BL-2/ABL-2
2. Whether or not the vector is generated using adenovirus or any other helper virus of human origin
3. Identification of the cell line in which the vector is propagated
4. A description of purification procedures (e.g.: column chromatography, etc.) and/or documentation from the source of the vector (investigator or vector core facility) that describes purification procedures
5. Animal bedding must be decontaminated prior to disposal for the first 72 hours after final injection and first cage change. Necropsy and postmortem tissue handling of animals receiving direct injection of AAV as described above can be performed under BL-1 conditions 72 hours after final injection.

**Sec. XI-B. Biosafety Level 1**

Follow practices as described below

Deviate from practices described below, please explain:

Standard Biosafety Level 1 practices:

1. Personal Protective Equipment (PPE): PPE such as gloves, safety glasses and a laboratory coat should be worn whenever biological work is conducted in the laboratory. No sandals are allowed in the laboratory. No open-toed shoes, ballet flats, shorts, or short skirts are allowed in the laboratory for all biosafety levels.
2. Handwashing: Hands must be washed immediately or as soon as feasible after removing gloves or other personal protective clothing.
3. Use of Sharps: Minimize the use of and exposure to sharps in the workplace. Never recap, bend or shear needles. As often as possible, replace glassware with less damaging materials such as plastic. Keep sharps containers readily available in all locations where sharps waste may be generated. In order to avoid accidental injury, do not overfill sharps containers.
4. Food and Beverage: Eating, drinking, storing food and drink for human consumption, smoking, applying cosmetics or lip balm and handling contact lenses in the laboratory or other work areas is prohibited. This prohibition shall be well posted.
5. Aerosol Generation: Any procedures that could potentially generate aerosols or other inhalation hazards must be performed in a manner that will minimize airborne pathogen transmission.
6. Proper Labeling: Place a color-coded label incorporating the universal biohazard symbol on any potentially contaminated equipment or work surface to warn others of biohazard contamination that may not be easily visible. This includes freezers, refrigerators and incubators.
7. Autoclave Safety: Always wear heat-resistant gloves, goggles or safety glasses, and a laboratory coat when opening an autoclave. Be sure to allow the superheated steam to exit before attempting to remove the contents.
8. Spills: Always clean spills from the periphery of the spill towards the center, after placing paper towels over the spill. Make sure that the cleaning materials are disposed of in an appropriate manner. Report all spills to the Biological Safety Office.
9. Mouth Pipetting: Mouth pipetting may lead to accidental ingestion of biological specimens and is strictly prohibited.
10. Decontamination Procedures: A fresh 0.5 – 1 percent sodium hypochlorite (a 1 to 10-20 dilution of household bleach) will be used to decontaminate equipment, work surfaces, and liquid waste. In locations where bleach would cause corrosion, an iodophor (e.g., Wescodyne) will be used to decontaminate. All solid waste shall be autoclaved prior to disposal.
11. Local Transport of Biological Materials: All biological materials transported to and from the laboratory will be enclosed in a primary container with a sealed lid or top, which will then be enclosed in a secondary leak-proof, rigid container (e.g., a Coleman cooler) appropriately labeled with biohazard symbol. A responsible lab employee shall escort any specimens transported to and from off-campus satellite facilities.
12. Storage: All infectious materials to be stored will be clearly labeled with the universal biohazard symbol as will the storage space (e.g., freezers and refrigerators).

**Sec. XI-C. Biosafety Level 2**

Follow practices as described below **in addition to** the Biosafety Level 1 practices listed above

Deviate from practices described below, please explain:

Standard Biosafety Level 2 practices:

1. Use of Sharps: Minimize the use of and exposure to sharps in the workplace. Never recap, bend or shear needles. As often as possible, replace glassware with less damaging materials such as plastic. Keep sharps containers readily available in all locations where sharps waste may be generated. In order to avoid accidental injury, do not overfill sharps containers.
2. Attention to sharps; use of safety needles when possible
3. Local Transport of Infectious Materials: All infectious materials transported to and from the laboratory will be enclosed in a primary container with a sealed lid or top, which will then be enclosed in a secondary leak-proof, rigid container (e.g., a Coleman cooler) appropriately labeled with biohazard symbol. A responsible lab employee shall escort any specimens transported to and from off-campus satellite facilities. Packaging and labeling must comply with the IATA dangerous goods or DOT hazardous materials regulations.
4. Bloodborne Pathogens: All PIs using human blood or blood products, unfixed tissue, body fluids or organ or cell cultures of human origin will follow the procedures outlined in the Marian University Chemical Hygiene Plan.
5. No plants shall be allowed in the laboratory.
6. Transport of Select Agents/Toxins: The Laboratory Safety & Chemical Hygiene Officer must be notified of all transfers or shipments off campus.
7. The PI is responsible for developing laboratory SOPs and training laboratory staff in specific procedures.
8. Procedures with a potential for creating aerosols or splashes must be conducted inside a biological safety cabinet or with other appropriate personal protective equipment as determined by the Chemical Hygiene Officer.

**Sec. XI-D. Biosafety Level 3**

Follow practices as described below **in addition** to the Biosafety Level 1 and 2 listed above

Deviate from practices described below, please explain:

All BL3 procedures, training and safety precautions have been documented and reviewed by the MU-IBC.

**Section XII. Personal Protective Equipment (PPE) & Laboratory Practices**

**Sec. XII-A. Personal Protective Equipment (PPE)** **and Safety Equipment** (*check [X] for all that apply):*

Non-Animal Research

Gloves  Eye Protection  Laboratory Coat

Face Shield  Surgical Mask  Respirator:

Chemical Fume Hood\*  Biosafety Cabinet  Other PPE:

\* Check Chemical Fume Hood only if hood is being used for biological work.

Animal Research (Vertebrate research only)

Gloves  Eye Protection  Disposable Gown

Face Shield  Surgical Mask  Respirator:

Chemical Fume Hood\*  Biosafety Cabinet  Other PPE:

Method of animal containment/caging:

\* Check Chemical Fume Hood only if hood is being used for biological work.

Hypoxia Chamber

My lab is using a hypoxia chamber. If checked, please complete the questions below.

Make/Model of Chamber:

Please describe any in-house modifications to chamber:

Agents that will be used inside the chamber:

Procedures that will occur within the chamber (including duration):

Decontamination Procedure:

Spill Procedures:

**Sec. XII-B. Laboratory Practices** (*check [X] for all that apply):*

Needles and syringes are not recapped or reused

Restrictions on the use of sharps while working with the following agent(s):

Sharp containers are only 2/3 full before disposal

Chemical restraint (animals)

Physical Restraint (animals)

Biological material transported outside of the laboratory in rigid container with lid and biohazard symbol

Biological material transported outside of the laboratory in other container (describe):

Vortexing/mixing/centrifugation performed in tightly capped tubes

Centrifugation performed in aerosol containment capsules (Check box if Inhalation is checked as a route of Transmission in Sec.V.A.)

Specialized spill procedures required (Check box if Inhalation is checked as a Route of Transmission in Sec.V.A.): Evacuate immediate area for 30 minutes, post signage on all entrances and Campus Police.

Pipetting in Biosafety Cabinet for work requiring BSL-2 or higher containment

Other Techniques performed in Biosafety Cabinet:

Other Techniques performed on bench top:

**Sec. XII-C. Laboratory Access** (*check [X] for all that apply):*

Limited to personnel listed on protocol

Locked laboratories with limited public access

Limited to personnel trained for specific procedure

Other:

**Sec. XII-D. Health Surveillance/Immunization** (*check [X] for all that apply):*

Hepatitis B Vaccine offered

Orthopoxviruses (vaccinia and others)

Other Vaccine:

Custom health surveillance/immunization program:

Serum sample banking: *Please note that Marian University* ***does not*** *have a serum banking program in place. If this is required to ensure the health and safety of employees, please reach out to the Chair of the Marian University Biosafety Committee (IBC@marian.edu).*

**Section XIII. Decontamination and Waste Disposal Procedures**

**Sec. XIII-A. Lab or Surface Disinfectant** (*check [X] all that apply):*

10% commercial bleach (0.5% sodium hypochlorite) with 10 minutes contact time

70% Ethanol with 10 minutes contact time

Other Disinfectant: Contact Time:

Concentration:

**Sec. XIII-B. Solid Waste** (*check [X] all that apply):*

Materials will be autoclaved for a minimum of 15 minutes, at 121°C, under 15 psi (pounds per square inch)

Chemical Inactivation: Chemical: Contact Time:

Other:

Mammalian/avian animal carcasses are frozen, EHS is contacted to pick them up and dispose of them (Bloomington)

Animal carcasses are returned to animal facility for disposal in accordance with IACUC policies.

Animal carcass, including invertebrate, disposal, Other:

**Sec. XIII-C. Liquid Waste** (*check [X] all that apply):*

Commercial bleach (equivalent to .5% sodium hypochlorite), with 30 minutes contact time

*\*Note: Final concentration of bleach after addition of biological research materials should be at least 10%\**

Other:

**Sec. XIII-D. Infectious Sharps** (*check [X] all that apply):*

Puncture resistant container with a biohazard symbol: autoclaved prior to disposal

**Sec. XIII-E. Equipment Decontamination Procedure**

Please detail how you will decontaminate equipment:

**Section XIV. Reporting**

By signing this form, I agree to abide by all university and federal guidelines and regulations regarding recombinant or synthetic nucleic acid molecules, infectious agents, and/or human tissues and fluids in research.

Marian University researchers and affiliates must immediately report to the Chemical Hygiene Officer any one or more of the following events:

* Any incident which results in the release of recombinant DNA or synthetic nucleic acid molecules to the environment (including escape of a transgenic animal)
* Any spill of recombinant DNA-containing material outside of a biological safety cabinet.
* Any research-related incidents and illnesses (including needle sticks and bites from transgenic or infected animals).
* Spills and accidents involving wild type infectious organisms, organisms containing recombinant or synthetic nucleic acid molecules, or potentially infectious material which result in overt personnel exposure.
* Spills and accidents in any NIH nonexempt animal laboratory that result in environmental release or exposures of animals or laboratory workers to organisms containing recombinant or synthetic nucleic acid molecules.
* Any problems at any biosafety level pertaining to the operation and implementation of containment practices and procedures, violations of the *NIH Guidelines.*

**By checking this box, I understand that I am responsible for ensuring compliance with all applicable regulations and the terms of protocol approval.**

**Section XV. Investigator Statement & Signature**

The Principal Investigator is responsible for providing adequate training and supervision of staff in microbiological techniques and practices required to ensure safety and for procedures in dealing with accidents. The investigator is responsible for enforcing federal regulations regarding laboratory safety for all persons who work under his/her direction. The investigator is responsible for correcting work errors and conditions that may result in the release of recombinant DNA or synthetic nucleic acid materials, biohazardous materials, or infectious agents and ensuring the integrity of the physical containment. Any work-related injury or exposure must be reported to Human Resources as soon as it is safe and practical to do so. The investigator is also responsible for ensuring that co-investigators, if any, employ the necessary safeguards to protect laboratory personnel, students, and the community from potential hazards posed by the project. The investigator must ensure that staff has read this protocol and the Marian University Chemical Hygiene Plan.

I certify that I have read the above statements and agree that I and all listed participants will abide by those statements as well as all university and campus policies and procedures governing the use of infectious agents and other biological materials as outlined in this application and in the Marian University Chemical Hygiene Plan.

In addition, I will:

* Abide by the General Duty Clause of OSHA and take full responsibility to ensure that listed personnel have received or will receive appropriate training in safe laboratory practices and procedures for this protocol before any work begins on this project and at least annually thereafter. Also, all listed personnel who have occupational exposure to bloodborne pathogens will be trained annually;
* Follow the health surveillance practices as approved for this protocol and inform those working on the protocol about appropriate emergency assistance information for their location(s);
* Inform Employee Health Services, the IBC and the NIH OBA of any research-related accident or illness as soon as possible after its occurrence as per [*NIH Guidelines*](https://osp.od.nih.gov/biotechnology/nih-guidelines/) Section IV-B-7-e-(2);
* Submit in writing a request for approval from the IBC of any significant modifications to the protocol, facilities or procedures; and;
* Adhere to campus-specific Biosafety guidelines referred to in this application as well as comply with the requirements of the Marian University Chemical Hygiene Plan.

I understand my responsibility regarding laboratory safety and certify that the protocol as approved by the IBC will be followed during the period covered by this research project. Any future changes will be submitted for IBC review and approval prior to implementation.

To ensure that the IBC has the most current information when reviewing a protocol, it has established a 3-year resubmission policy for on-going IBC protocols. The policy requires principal investigators (PIs) to submit a new protocol to the IBC in lieu of the third annual continuing review. I understand that this protocol will also be reviewed periodically; it is my responsibility to complete and submit the survey form used for the periodic IBC review in a timely manner. I will resubmit a full application every 3 years as is IBC policy.

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Principal Investigator Signature Protocol Submission Date

Type name above and check for electronic signature

**IBC OFFICE USE ONLY**

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Biosafety Office Representative (if applicable) Approval Date

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Institutional Biosafety Committee Member (if applicable) Approval Date

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Office of Research Compliance Final Approval Date