# Section 1: Overview, Principal Investigator, and Assurance Statement

## Overview: All researchers or instructors planning to work with biological agents, biological toxins, viruses, pathogens, recombinant DNA or synthetic nucleic acids must complete all applicable sections of this form. Sections that do not apply to the intended work may be left blank. Once a protocol is reviewed and registered by the IBC, an IBC Modification Request Form and an amended protocol should be submitted to request approval for any changes to the protocol. Approved protocols expire after three years.

Submit completed form electronically to ibc@butler.edu. Investigators should keep a copy of the protocol in their records as well as placing a copy in their lab for all staff listed on this protocol to review.

## Project Identification: Type: [ ]  Research [ ]  Teaching

|  |
| --- |
| **Protocol Title:** |
| **Principal Investigator / Instructor**: |
| Department: | Building/Lab Room: |
| Phone No: | Email: |
| **Co-Principal Investigator / Instructor**: |
| Department / Division: | Building / Lab Room: |
| Phone No: | Email: |
| Type of Review: [ ]  New Submission [ ]  3 Year Renewal [ ]  Revision/Resubmission |
| Funding Agency (if applicable)  |

## Principal Investigator or Instructor Assurance Statement:

By signing below I am agreeing that:

[ ]  The information provided is true and accurate. I acknowledge I have familiarized myself with the [NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules](http://osp.od.nih.gov/sites/default/files/resources/NIH_Guidelines_PRN_1-sided.pdf) (NIH Guidelines) as it relates to the biological materials described in this application and I am aware that my intended work will be subject to these guidelines and the [*Biosafety in Microbiological and Biomedical Laboratories manual*](https://www.cdc.gov/biosafety/publications/bmbl5/BMBL.pdf) (BMBL).

[ ]  I will not begin any of the procedures or activities outlined in this protocol until I have contacted the Institutional Biosafety Committee (IBC).

[ ]  I ensure that personnel under my oversight, including staff and students, have received training appropriate to their work activities and have also received information on proper signage, potential biological hazards (as outlined in this protocol), manuals, Standard Operation Procedure (SOP), and other information for these employees to safely and effectively perform their job duties. I also will ensure that these personnel will keep up do date on the required training.

[ ]  I will ensure that personnel under my oversight understand procedures for dealing with incidents and biological material spills and know proper waste management and spill cleanup procedures.

[ ]  I will comply with the OSHA Bloodborne Pathogen Standard 29 CFR 1910.1030 if I plan to work with human-derived materials such as cells, tissues, organs, or embryonic stem cells.

[ ]  I ensure that all spaces where the intended work will be conducted are listed in this protocol.

Signature of PI and/or Instructor: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_

Signature of Co-PI and/or Instructor: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_

# Section 2: Biological Material Categories and Experimental Design

## Biological Material Categories:

**Check all of the materials below that will be used in your study**:

[ ]  Bacteria, Viruses, Viral Vectors, Fungi, Prions

[ ]  Human/Non-Human Primate (NHP) Cell Lines, Tissues, or Blood Products

[ ]  Animal Cell Lines, Tissues, or Blood Products

[ ]  Plants (exotic or grown in association with pathogenic or recombinant microbes/animals)

[ ]  Biological Toxins

[ ]  Recombinant DNA (rDNA)

[ ]  Live Animals (vertebrate or invertebrate)

## Experimental Design: Briefly describe the experimental design. Include a brief description of how the materials indicated above will be used in this protocol using language a non-expert would understand. Explain the class objective if this is a protocol specifically for a teaching laboratory.

|  |
| --- |
|  |

# Section 3: Personnel, Responsibilities, and Training

## Personnel, Responsibilities, and Training: Identify all personnel (including students) who will be working with any of the biological materials described on this protocol, indicate the training they have received, and their responsibilities under this protocol. Attachments are acceptable (e.g. class roster).

|  |  |  |
| --- | --- | --- |
| **Name** | **Responsibilities**(N/A if none) | **Training Completed**(e.g., CITI trainings, BBP\*, rDNA)\*BBP = Blood bone Pathogen |
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**Additional Information:** Indicate the following:

|  |
| --- |
| 1. *Individual(s) responsible for training all incoming laboratory personnel:*
2. *Individual(s) responsible for training-Years of experience for handling the biological materials indicated on this protocol:*
3. *How and where completed training is documented:*
4. *Other information:*
 |

## Students and Teaching Activities: Complete the section only if this protocol covers teaching activities. Provide a summary of the training provided to students who will be involved with the classroom activities. Include any hands-on training, instructor-based training, or online learning. Include which classes the students are participating in for these procedures:

|  |
| --- |
|  |

# Section 4: Locations

## Locations: List all locations where biological materials will be used, stored, or handled.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Building** | **Room** | **Use of Room**(e.g. classroom, laboratory, animal housing, storage) | **Containment Level**(e.g. BL-1, ABSL-1\*)\*ABSL= Animal Biosafety Level | **Containment Equipment**(e.g. BSC, fume hood) |
| 1. |  |  |  |  |
| 2. |  |  |  |  |
| 3. |  |  |  |  |
| 4. |  |  |  |  |
| 5. |  |  |  |  |
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| 8. |  |  |  |  |
| 9. |  |  |  |  |
| 10. |  |  |  |  |

# Section 5: NIH Guidelines and Recombinant Materials

## NIH Guidelines: If you intend to use rDNA materials in protocol, indicate all citations from Section III of the NIH Guidelines that apply to your research. Check N/A if you are not using rDNA materials in this protocol and continue to Section 5B.

[ ]  **N/A**

|  |  |
| --- | --- |
|[ ]  III-A-1 | The deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire that trait naturally, if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture. |
|[ ]  III-B-1 | Deliberate formation of rDNA containing genes for the biosynthesis of toxin molecules lethal for vertebrates at an LD50 of less than 100 nanograms per kilogram body weight. |
|[ ]  III-B-2 | Experiments that have been Approved (under Section III-A-1-a) as Major Actions under the NIH Guidelines and determined by NIH/OBA. |
|[ ]  III-C-1 | Experiments involving the Deliberate Transfer of Recombinant or Synthetic Nucleic Acid Molecules, or DNA or RNA Derived from Recombinant or Synthetic Nucleic Acid Molecules, into One or More Human Research Participants. |
|[ ]  III-D-1 | Experiments using Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents as Host-Vector Systems. |
|[ ]  III-D-2 | Experiments in which DNA from Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents is Cloned into Nonpathogenic Prokaryotic or Lower Eukaryotic Host-Vector Systems. |
|[ ]  III-D-3 | Experiments involving the Use of Infectious DNA or RNA Viruses or Defective DNA or RNA Viruses in the Presence of Helper Virus in Tissue Culture Systems |
|[ ]  III-D-4 | Stable introduction of rDNA into an animal genome or testing of rDNA-modified microorganisms in whole animals. |
|[ ]  III-D-5 | Experiments to genetically engineer plants by rDNA methods, to use such plants for other experimental purposes (e.g., response to stress), to propagate such plants, or to use plants together with microorganisms or insects containing rDNA. |
|[ ]  III-D-6 | Experiments involving more than 10 Liters of Culture (in a single vessel)**If Checked, Indicate Biological Material(s) Here:** |
|[ ]  III-D-7 | Experiments involving Influenza Viruses |
|[ ]  III-E | Experiments not included in Sections III-A, III-B, III-C, III-D, III-F and their subsections |
|[ ]  III-E-1 | Formation of rDNA molecules containing no more than 2/3 of any eukaryotic viral genome |
|[ ]  III-E-2 | Experiments with genetically modified plants |
|[ ]  III-E-3 | Experiments involving the generation of transgenic rodents |
|[ ]  III-F-1 | Those synthetic nucleic acids that: (1) can neither replicate nor generate nucleic acids that can replicate in any living cell (e.g., oligonucleotides or other synthetic nucleic acids that do not contain an origin of replication or contain elements known to interact with either DNA or RNA polymerase. |
|[ ]  III-F-2 | Those that are not in organisms, cells, or viruses and that have not been modified or manipulated (e.g., encapsulated into synthetic or natural vehicles) to render them capable of penetrating cellular membranes. |
|[ ]  III-F-3 | Those that consist solely of the exact recombinant or synthetic nucleic acid sequence from a single source that exists contemporaneously in nature. |
|[ ]  III-F-4 | rDNA molecules consisting entirely of DNA from a prokaryotic host including its indigenous plasmids or viruses where propagated only in that the host (or a closely related strain of the same species) or transferred to another host by know physiological means. |
|[ ]  III-F-5 | rDNA molecules consisting entirely of DNA from a eukaryotic host (including mitochondria, chloroplasts, or plasmids but excluding viruses) when propagated only in that host or a closely related strain of the same species. |
|[ ]  III-F-6 | rDNA molecules consisting entirely of DNA segments from different species that exchange DNA by known physiological processes and are described in Appendix A. |
|[ ]  III-F-7 | Those genomic DNA molecules that have acquired a transposable element provided the transposable element does not contain any recombinant and/or synthetic DNA. |
|[ ]  III-F-8 | Experiments not posing significant risk to health or the environment, as determined by the NIH Director, and are described in Appendix C of the NIH Guidelines.**Appendix C Reference**:[ ]  C-I: Recombinant or Synthetic Nucleic Acid Molecules in Tissue Culture[ ]  C-II: *E. coli* K-12 Host-Vector Systems[ ]  C-III: *Saccharomyces* Host-Vector Systems[ ]  C-IV: *Kluyveromyces* Host-Vector Systems[ ]  C-V: *Bacillus subtilis* or *Bacillus licheniformis* Host-Vector Systems[ ]  C-VI: Extrachromosomal Elements of Gram Positive Organisms[ ]  C-VII: The Purchase or Transfer of Transgenic Rodents[ ]  C-VIII: Generation of BL1 Transgenic Rodents via Breeding |

## Recombinant Materials: Describe the Recombinant or Synthetic DNA/RNA materials used in this protocol and attach the list of vectors. NOTE: It is not necessary to list antibiotic resistance genes in this subsection. Check N/A if you are not using Recombinant or Synthetic DNA/RNA materials in this protocol and continue to Section 6.

[ ]  **N/A**

|  |  |  |  |
| --- | --- | --- | --- |
|  **Name of Gene or****Gene Fragment**(e.g., microtubulin, GFP, Ras, Ampicillinr) | **Nature of Gene**(e.g., oncogene, toxin, transcription factor, tracking)  | **Source Organism**(*e.g., Enterococcus faecalis*, *Drosophila melanogaster )* | **Administered to**(e.g., *Enterococcus faecalis*, *Mus musculus*) |
| 1. |  |  |  |
| 2. |  |  |  |
| 3. |  |  |  |
| 4. |  |  |  |
| 5. |  |  |  |
| 6. |  |  |  |
| 7. |  |  |  |
| 8. |  |  |  |
| 9. |  |  |  |
| 10. |  |  |  |

# Section 6: Bacteria, Viruses, Viral Vectors, Fungi, and Prions

## Bacteria: Complete this subsection if working with any prokaryotes. Check N/A if you are not using any prokaryotes in this protocol, and continue to Section 6B.

[ ]  **N/A**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Genus and Species** | **NIH Risk Group (RG)\*** | **BSL** | **rDNA?**(Y/N; If “Y” include Section 5B reference) | **Administered to**(e.g., *Mus musculus)* |
| 1. |  |  |  |  |
| 2. |  |  |  |  |
| 3. |  |  |  |  |
| 4. |  |  |  |  |
| 5. |  |  |  |  |
| 6. |  |  |  |  |
| 7. |  |  |  |  |
| 8. |  |  |  |  |
| 9. |  |  |  |  |
| 10. |  |  |  |  |

***Note\*:*** *Please see NIH Guidelines for research involving recombinant or synthetic nucleic acid molecules, Appendix B - Classification of human etiologic agents on the basis of hazards.*

**Additional Information**: Provide additional information relevant to the bacteria listed.

|  |
| --- |
| 1. *Indicate routes of exposure and list PPE used to reduce exposure risk:*
2. *List possible consequences of an exposure:*
3. *List aerosol generating activities and how an exposure will be mitigated:*
4. *Indicate any antibiotic resistance markers used in Risk Group 2 or greater bacteria:*
5. *Other information:*
 |

## Viruses: Complete this section if you are working with any viruses (not including viral vectors). Check N/A if you are not using any viruses in this protocol, and continue to Section 6C.

[ ]  **N/A**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Name of Virus** | **RG** | **BSL** | **rDNA?**(Y/N; If “Y” include Section 5B reference) | **Administered to**(Cell Culture, *Mus musculus, Zea mays*) |
| 1. |  |  |  |  |
| 2. |  |  |  |  |
| 3. |  |  |  |  |
| 4. |  |  |  |  |
| 5. |  |  |  |  |
| 6. |  |  |  |  |
| 7. |  |  |  |  |
| 8. |  |  |  |  |

**Additional Information**: Provide additional information that is relevant to the viruses listed.

|  |
| --- |
| 1. *Indicate routes of exposure and list PPE used to reduce exposure risk:*
2. *List possible consequences of exposure:*
3. *List aerosol generating activities and how an exposure risk will be mitigated:*
4. *Indicate any drug resistance traits engineered into any virus Risk Group 2 or greater:*
5. *Other information:*
 |

## Viral Vectors: Complete this section if you are working with any viral vectors. Check N/A if you are not working with viral vectors in this protocol and continue to SECTION 6D.

## [ ]  N/A

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Viral Vector** | **Generation of Vector**(e.g., 3rd) | **RG** | **BSL** | **rDNA Listed in Section 5B**(e.g., #5, #8) | **Administered to**(Cell Culture, *Mus musculus, Zea mays*) |
| 1. |  |  |  |  |  |
| 2. |  |  |  |  |  |
| 3. |  |  |  |  |  |
| 4. |  |  |  |  |  |
| 5. |  |  |  |  |  |
| 6. |  |  |  |  |  |
| 7. |  |  |  |  |  |
| 8. |  |  |  |  |  |
| 9. |  |  |  |  |  |
| 10. |  |  |  |  |  |

**Additional Information**: Provide additional information relevant to the viral vectors listed.

|  |
| --- |
| 1. *Indicate routes of exposure and list PPE used to reduce exposure risk:*
2. *List possible consequences of exposure:*
3. *List aerosol generating activities and how an exposure risk will be mitigated:*
4. *Other information:*
 |

## Fungi: Complete this subsection if working with any fungi. Check N/A if you are not working with fungi in this protocol, and continue to Section 6E.

[ ]  **N/A**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Fungi**(Common Name; Genus species) | **RG** | **BSL** | **rDNA?**(Y/N; If “Y” include Section 5B reference) | **Administered to**(e.g., *Mus musculus)* |
| 1. |  |  |  |  |
| 2. |  |  |  |  |
| 3. |  |  |  |  |
| 4. |  |  |  |  |
| 5. |  |  |  |  |
| 6. |  |  |  |  |
| 7. |  |  |  |  |
| 8. |  |  |  |  |
| 9. |  |  |  |  |
| 10. |  |  |  |  |

 **Additional Information**: provide additional information that is relevant to the fungi listed.

|  |
| --- |
| 1. *Indicate routes of exposure and list PPE used to reduce exposure risk:*
2. *List possible consequences of exposure:*
3. *List aerosol generating activities and how an exposure risk will be mitigated:*
4. *Indicate any antibiotic resistance markers used in Risk Group 2 or greater fungi:*
5. *Other information:*
 |

## Prions: Complete this subsection if working with any prions. Check N/A if you are not working with prions in this protocol, and continue to Section 7.

[ ]  **N/A**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Common Name and Affected Species** | **RG** | **BSL** | **Recombinant** (Y/N) | **Administered to**(e.g., *Mus musculus)* |
| 1. |  |  |  |  |
| 2. |  |  |  |  |
| 3. |  |  |  |  |
| 4. |  |  |  |  |
| 5. |  |  |  |  |
| 6. |  |  |  |  |
| 7. |  |  |  |  |
| 8. |  |  |  |  |
| 9. |  |  |  |  |
| 10. |  |  |  |  |

 **Additional Information**: Provide additional information that is relevant to the prions listed.

|  |
| --- |
| 1. *Indicate routes of exposure and list PPE used to reduce exposure risk:*
2. *List possible consequences of exposure:*
3. *List aerosol generating activities and how an exposure risk will be mitigated:*
4. *Other information:*
 |

# Section 7: Human / Non-Human Primate and Animal Cell Lines, Tissues, or Blood Products

## Human / Non-Human Primate Cell Lines, Tissues or Blood Products: Complete this subsection if working with any human or non-human primate derived materials. List the type of material used. Example: list “human pancreatic cells” and not specific human pancreatic cell lines such as “AKT2” or “HTB-134” unless the specific cells pose a unique hazard. Check N/A if you are not using human or non-human primate derived materials in this protocol, and continue to Section 7B.

[ ]  **N/A**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Type of Material** | **Fetal Derived?** (Y/N) | **BSL** | **rDNA?**(Y/N; If “Y” include Section 5B reference) | **Administered to**(e.g., *Mus musculus)**If applicable*  |
| 1. |  |  |  |  |
| 2. |  |  |  |  |
| 3. |  |  |  |  |
| 4. |  |  |  |  |
| 5. |  |  |  |  |
| 6. |  |  |  |  |
| 7. |  |  |  |  |
| 8. |  |  |  |  |
| 9. |  |  |  |  |
| 10. |  |  |  |  |

**Additional Information**: Provide additional information relevant to the cells, tissues or blood

products listed.

|  |
| --- |
| 1. *Indicate routes of exposure and list PPE used to reduce exposure risk:*
2. *List possible consequences of exposure:*
3. *List aerosol generating activities and how an exposure risk will be mitigated:*
4. *Other information:*
 |

## Animal Cell Lines, Tissues or Blood Products: Complete this subsection if working with any animal cell lines, tissues or blood products. List the type of material used; example: list “mouse pancreatic cells” and not specific mouse pancreatic cell lines such as “CRL-2151” or “CRL-2135” unless the specific cells pose a unique hazard. Check N/A if you are not using animal cell lines, tissues or blood products in this protocol, and continue to Section 8.

[ ]  **N/A**

|  |  |  |  |
| --- | --- | --- | --- |
| **Type of Material** | **BSL** | **rDNA?**(Y/N; If “Y” include Section 5B reference) | **Administered to**(e.g., *Mus musculus)* |
| 1. |  |  |  |
| 2. |  |  |  |
| 3. |  |  |  |
| 4. |  |  |  |
| 5. |  |  |  |
| 6. |  |  |  |
| 7. |  |  |  |
| 8. |  |  |  |
| 9. |  |  |  |
| 10. |  |  |  |

**Additional Information**: Provide additional information relevant to the cells, tissues or blood

products listed.

|  |
| --- |
| 1. *Indicate routes of exposure and list PPE used to reduce exposure risk:*
2. *List possible consequences of exposure:*
3. *List aerosol generating activities and how an exposure risk will be mitigated:*
4. *Other information:*
 |

# Section 8: Biological Toxins

## Biological Toxins: Complete this subsection if working with any toxins of biological origin e.g. Abrin, Botulinum neurotoxins, Ricin, T-2 toxin etc. Check N/A if you’re nor using toxins of biological origin in this protocol, and continue to Section 9.

[ ]  **N/A**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Biological Toxin** | **LD50**(ng/kg) | **BSL** | **Select Toxin?** (Y/N) | **Administered to**(e.g., *Mus musculus)* | **Max Amount Administered**(at one time) |
| 1. |  |  |  |  |  |
| 2. |  |  |  |  |  |
| 3. |  |  |  |  |  |
| 4. |  |  |  |  |  |
| 5. |  |  |  |  |  |
| 6. |  |  |  |  |  |
| 7. |  |  |  |  |  |
| 8. |  |  |  |  |  |
| 9. |  |  |  |  |  |
| 10. |  |  |  |  |  |

**Additional Information**: Provide additional information relevant to the biological toxins listed.

|  |
| --- |
| 1. *Indicate routes of exposure and list PPE used to reduce exposure risk:*
2. *For each Select Toxin- Indicate maximum amount of toxin in inventory, and where inventory is documented:*
3. *Describe how each toxin will be inactivated:*
4. *For toxins that will be reconstituted from a powder-describe process for reconstitution:*
5. *List aerosol generating activities and how an exposure risk will be mitigated:*
6. *Other information:*
 |

# Section 9: Vertebrate and Invertebrate Animals

## Vertebrates: Complete this subsection for vertebrate animals administered biological materials. Note: IACUC approval is required prior to initiating work involving vertebrate animals. Check N/A if you are not using vertebrate animals in this protocol, and continue to Section 9B.

[ ]  **N/A**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Vertebrate**(Common Name; Genus species) | **Animal Biosafety Level** | **Transgenic?** (Y/N) | **Biological Materials Administered**Section 5B ref) | **Housing**(e.g., *static microisolators, rack system)* |
| 1. |  |  |  |  |
| 2. |  |  |  |  |
| 3. |  |  |  |  |
| 4. |  |  |  |  |
| 5. |  |  |  |  |
| 6. |  |  |  |  |
| 7. |  |  |  |  |
| 8. |  |  |  |  |
| 9. |  |  |  |  |
| 10. |  |  |  |  |

**Additional Information**: Provide additional information relevant to vertebrate animals listed.

|  |
| --- |
| 1. *Indicate routes of shedding for any biological material administered:*
2. *List PPE used to reduce exposure risk:*
3. *Indicate the period of infectivity and shedding for any biological material administered:*
4. *List aerosol generating activities involving biological materials and how an exposure will be mitigated:*
5. *Other information:*
 |

## Invertebrates: Complete this subsection if working with any invertebrate animals. Check N/A if you are not using vertebrate animals in this protocol, and continue to Section 10.

##  [ ]  N/A

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Invertebrate**(Common Name; Genus species) | **Animal Biosafety Level** | **Transgenic?** (Y/N) | **Biological Materials Administered**(Section 5B ref)  | **Housing**(e.g., *petri dish, aquarium)* |
| 1. |  |  |  |  |
| 2. |  |  |  |  |
| 3. |  |  |  |  |
| 4. |  |  |  |  |
| 5. |  |  |  |  |
| 6. |  |  |  |  |
| 7. |  |  |  |  |
| 8. |  |  |  |  |
| 9. |  |  |  |  |
| 10. |  |  |  |  |

**Additional Information**: Provide additional information relevant to invertebrate animals listed.

|  |
| --- |
| 1. *Indicate routes of exposure for any biological material administered:*
2. *List PPE used to reduce exposure risk:*
3. *Indicate the period of infectivity and shedding for any biological material administered:*
4. *List aerosol generating activities involving biological materials and how an exposure risk will be mitigated:*
5. *Other information:*
 |

# Section 10: Plants

## Plants: Complete this subsection if working with any exotic or invasive plants, plants that are grown in association with pathogenic or recombinant microbes, or pathogenic or recombinant animals (e.g., insects). Check N/A if you are not using exotic or invasive plants in this protocol, and continue to Section 11.

[ ]  **N/A**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Plant** (Common Name; Genus species) | **Plant Biosafety Level** | **Transgenic?** (Y/N) | **Biological Materials Administered**(Section 5B ref) | **Growth Location**(e.g., *greenhouse, growth chamber location)* |
| 1. |  |  |  |  |
| 2. |  |  |  |  |
| 3. |  |  |  |  |
| 4. |  |  |  |  |
| 5. |  |  |  |  |

**Additional Information**: Provide additional information relevant to vertebrate animals listed.

|  |
| --- |
| 1. *Indicate routes of exposure for any biological material administered:*
2. *List PPE used to reduce exposure risk:*
3. *Indicate precautions used to contain transgenic plants:*
4. *List aerosol generating activities involving biological materials and how an exposure risk will be mitigated:*
5. *Other information:*
 |

# Section 11: Emergency Response

## Emergency Response: Provide a general response procedure to be followed if an individual is accidentally exposed to any of the materials listed in this protocol. Consider the consequences of an accidental exposure (e.g., splash to the eye or mucous membranes, inoculation) which might occur during work with the materials outlined in this protocol.

|  |
| --- |
| 1. *Immediate response to an exposure:*
2. *Individuals to contact (including contact information) after an exposure:*
3. *Possible exposure outcomes to materials listed in this protocol:*
4. *Other information:*
 |

# Section 12: Waste Disposal, Spill Response, Surface Decontamination, and Laundry Service

## Waste Disposal: There are two recommended methods to dispose of biological waste, depending on the waste type:

* **Liquid Waste**:expose liquids to 10% bleach for 30 minutes prior to disposal in the sanitary sewer.
* **Solid Waste**: autoclave solid waste minimally at 121°C /30 minutes /2ATM.

**Do you plan to use the recommended waste disposal method indicated above for all materials (not including vertebrate animals) listed in this application?**

[ ]  **Yes** [ ]  **No**

If “no” was selected, describe the method used to dispose of the biological wastes that will not be disposed of using the above indicated methods:

|  |
| --- |
|  |

## Surface Decontamination: The following is the recommended procedure for decontamination surfaces that may have been exposed to biological materials:

1. Apply at least 10% bleach to surface and allow to air dry.
2. Apply 70% EtOH or water to surface to remove bleach residue.

**Do you plan to use the recommended surface decontamination method for all surfaces and equipment that may have been exposed to any of the materials listed in this application?**

[ ]  **Yes** [ ]  **No**

If “no” was selected, describe the method used to decontaminate the biological wastes that will not be disposed of using the above indicated method:

|  |
| --- |
|  |

## Spill Response: The following is the recommended procedure for decontaminating a spill outside of containment:

1. Notify supervisor and lab members of spill and close off area to traffic; for large spills of >100ml, leave room for 30 minutes to allow aerosols to settle.
2. Remove all contaminated clothing and place in biohazard bag for autoclaving, wash any exposed skin with soap and water, and wash exposed eyes for 10 minutes in eyewash.
3. Contact local medical service if an exposure requires emergency medical attention (Call 911).
4. Contact University Police (BUPD) at 940-2873 if necessary to request assistance limiting access to spill.
5. Put on any required Personal Protective Equipment (PPE). Do not attempt cleanup if adequate PPE is not available.
6. Cover the spill with absorbent material (e.g., paper towel).
7. Prepare fresh bleach solution (at least 10%).
8. Gently pour bleach solution on spill, starting from outside of spill.
9. Add more paper towels as necessary to contain liquid.
10. Allow 30 minutes contact time for bleach to decontaminate spill.
11. Clean up any broken glass with dust pan or forceps and dispose in glass waste container; any glass not yet decontaminated can be placed in a container (e.g., beaker) for decontamination with a 10% bleach solution.
12. Clean up paper towels and dispose in a biological waste container.
13. Report to IBC at ibc@butler.edu within 5 days of the incident.

**Do you plan to use the recommended spill clean up method indicated above for all materials listed in this application?**

[ ]  **Yes** [ ]  **No**

If “no” was selected, describe the method used to clean up biological spills outside of containment:

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| --- |
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## Laundry Service: Provide information on how laundry services are obtained for lab coats or other contaminated clothing (lab coats and contaminated clothing shall not be laundered at home).

|  |
| --- |
|  |

# Section 13: Transport and Shipping

Complete this section if you plan to transport any biological agents, toxins, viruses, pathogens, rDNA through public spaces on campus or ship biological materials. **Check N/A if you are not planning to transport any biological agents, toxins, viruses, pathogens, rDNA through public spaces on campus, or to ship biological materials, and continue to Section H.**

[ ]  **N/A**

## Transport: The following is the recommended method for transport of biological materials through public spaces:

1. Place biological material in a 1° and 2° container.
2. Place absorbent materials between 1° and 2° container sufficient to absorb contents of 1° container.
3. Place biohazard sticker on outermost container if transporting biohazardous material.

**Do you plan to use the recommended method to transport biological materials through public spaces?**

[ ]  **Yes** [ ]  **No**

If “no" was selected, describe the method used to transport or ship biological materials:

|  |
| --- |
|  |

## Shipping: The following is the recommended method for shipping biological materials:

1. Place biological material in a 1° and 2° container.
2. Place absorbent materials between 1° and 2° container sufficient to absorb contents of 1° container.
3. Place 1° and 2° container into 3° container.
4. Place applicable shipping label(s) on outside of 3° container.

**Do you plan to use the recommended method to ship biological materials?**

[ ]  **Yes** [ ]  **No**

If “no" was selected, describe the method used to transport or ship biological materials:

|  |
| --- |
|  |

# Section 14: Biological Material Storage Only

## Biological Material Storage Only: List all biological materials that will not be actively used, and that will only be maintained in storage. Check N/A if you are not using biological material storage for this protocol, and continue to Section 15.

[ ]  **N/A**

|  |  |  |  |
| --- | --- | --- | --- |
| **Biological Material** | **rDNA?**(Y/N/NA) | **Select Agent or Toxin** (Y/N/NA) | **Storage Location**(e.g., Building, Room, Freezer, Refrigerator) |
| 1) |  |  |  |
| 2) |  |  |  |
| 3) |  |  |  |
| 4) |  |  |  |
| 5) |  |  |  |
| 6) |  |  |  |
| 7) |  |  |  |
| 8) |  |  |  |
| 9) |  |  |  |
| 10) |  |  |  |

**\***If more space is needed, please attach additional page in the same format.

# Section 15: Additional Documents

## Additional Documents: Attach all documents necessary for a full review of this application.

Examples of documents to attach include the following:

* Lab manual(s)
* Standard Operating Procedures (SOP’s) describing experiment details related to materials handling
* Plasmid vector maps (backbone only required; type of insert is listed in Section 5B)
* Viral vector plasmid maps