**Section 1a: Basic contact information – IBC Administration (Required Section)**

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Application status: | |  | | Registration #: | | | Enter here | For IBC use only – Do not mark in this area | | | |
| New Submission | | | |  |  | | Registration #: |  | | |
|  | | | |  |  | |  |  | | |
| Renew Registration # | | Enter here |  | | | | Received Date: | | Version Date: | |
|  | |  | |  | | |  |  | |  |
| Amend Registration # | | Enter here | If checked, highlight the changes. | | | | | | | |

|  |  |
| --- | --- |
| Project Title: Enter here | |
| Principal Investigator: Enter here | Position Title: Enter here |
| Email Address: Enter here | Phone: Enter here |
| Department: Enter here | Location(s) of proposed research (Building and Room number(s): Enter here |
| Lab Contact (if other than PI): Enter here | Position Title: Enter here |
| Email Address: Enter here | Phone: Enter here |

|  |
| --- |
| **Principal Investigator’s Certification:**  I certify that I have read the following statements and agree that I and all listed personnel will abide by these statements:  As Principal Investigator for this project, I have the responsibility to ensure that my laboratory operates in a safe manner and that all staff and students are informed of risk, potential exposure routes, post exposure signs and symptoms, and safe handling procedures, and that they wear appropriate protective equipment and are adequately trained *before any work begins* and at least every three years thereafter. All listed personnel who have occupational exposure to bloodborne pathogens will be trained every three years (this training is available in CITI).  My laboratory has appropriate facilities, equipment, and work practices to conduct this work safely.  The following applicable biosafety guidelines have been reviewed:   * [University of Mississippi Biological Safety Manual](https://safety.olemiss.edu/safety-programs/biological-safety/biological-safety-manual/) * [NIH Guidelines for Research Involving Recombinant DNA Molecules](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf) * [CDC Biosafety in Microbiological and Biomedical Laboratories Manual, 6th Edition](https://www.cdc.gov/labs/pdf/SF__19_308133-A_BMBL6_00-BOOK-WEB-final-3.pdf) * [USDA/APHIS](https://www.aphis.usda.gov/laws-regs) * [NIH Dual Use Research of Concern](https://osp.od.nih.gov/policies/biosafety-and-biosecurity-policy/)   I will adhere to all applicable federal, state, and local laws and regulation, as well as all UM policies and guidelines, as IBC approval does not supersede other regulations, guidelines, or contracts.  I will comply with shipping requirements for hazardous materials including recombinant and/or synthetic nucleic acids and infectious agents.  I will inform those working on the protocol about appropriate injury and emergency response plans relevant to the area in which they work.  If my work involves recombinant or synthetic nucleic acid molecules, I acknowledge that I am responsible for full compliance with the NIH Guidelines in the conduct of recombinant and synthetic nucleic acid molecules research.  I will neither initiate nor modify any recombinant or synthetic nucleic acid molecules research subject to the NIH Guidelines until that research has been reviewed and approved by the IBC.  Registrations are renewed on a triennial basis. Changes in the project beyond the scope of this current registration require the submission of an amendment.  I will report the following to EH&S (662-915-5433) and IBC (662-915-5006 or [ibc@olemiss.edu](mailto:ibc@olemiss.edu)) as soon as possible:   1. Violations of the NIH Guidelines; 2. Biohazardous spills; 3. Loss of biohazard containment; 4. Research-related accidents or illnesses; 5. Exposures or potential exposures to biohazards, including recombinant or synthetic nucleic acid molecules; 6. Exposures or potential exposures involving animals previously exposed to biohazards, including recombinant or synthetic nucleic acid molecules.   In case of incidents, I will instruct my staff to complete the Online Accident Reporting System form within 24 hours. |
|  |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Signatures: | | | | | | | | | | | | |
|  | Principal Investigator: | Enter here | | | | | | | Date: | Enter here | | | |
|  | | | | | | | | | | | | | |
| **For IBC use only:** | | **IBC-**BSL **level approval** |  | **BSL-1** | |  | **BSL-1+** |  | **BSL-2** |  | **BSL-2+** |  | **BSL-3** |
| Do not mark in this area | | **IBC-**ABSL **approval** |  | **ABSL-1** | |  | **ABSL-1+** |  | **ABSL-2** |  | **ABSL-2+** |  | **ABSL-3** |
|  | | **IBC** BSL-P **approval** |  | **BSL-1P** | |  | **BSL-1+P** |  | **BSL-2P** | | | | |
|  | | **IBC Research Compliance Specialist:** | | |  | | | | | | | | |

**Section 1b: Basic contact information - Lab Personnel (Required Section)**

List all project personnel (PI, Associates, technicians, and students who will be involved in conducting the procedures or have access to the biological materials). This information is intended to inform the IBC of the training and background of key personnel. This is an IBC oversight activity required by the NIH Guidelines. Press the “+” in the bottom right corner to add additional personnel.

**All required training must be completed before the application can be reviewed.**

Name: Enter here Department: Enter here UM email: Enter here Title: Enter here

* 1. Describe the role this researcher will perform in this project: Click or tap here to enter text.
  2. Describe the researcher’s experience and qualifications related to the procedures that will be performed in this project. For personnel without prior relevant experience, state how they will be trained to work with biohazards in the laboratory, by whom that training is provided, and how it is determined that they are competent to conduct independent work with biohazards. Click or tap here to enter text.
  3. Has viewed the following biohazard CITI online training modules and successfully passed the corresponding quizzes (\*Required):

\*Initial Biosafety  \*Lab Chemical Safety  NIH rDNA Guidelines

OSHA Bloodborne Pathogens  Nanotechnology  Animal Biosafety

Select Agents, Biosecurity, and Bioterrorism  DURC

Name: Enter here Department: Enter here UM email: Enter here Title: Enter here

* 1. Describe the role this researcher will perform in this project: Click or tap here to enter text.
  2. Describe the researcher’s experience and qualifications related to the procedures that will be performed in this project. For personnel without prior relevant experience, state how they will be trained to work with biohazards in the laboratory, by whom that training is provided, and how it is determined that they are competent to conduct independent work with biohazards. Click or tap here to enter text.
  3. Has viewed the following biohazard CITI online training modules and successfully passed the corresponding quizzes (\*Required):

\*Initial Biosafety  \*Lab Chemical Safety  NIH rDNA Guidelines

OSHA Bloodborne Pathogens  Nanotechnology  Animal Biosafety

Select Agents, Biosecurity, and Bioterrorism  DURC

Name: Enter here Department: Enter here UM email: Enter here Title: Enter here

* 1. Describe the role this researcher will perform in this project: Click or tap here to enter text.
  2. Describe the researcher’s experience and qualifications related to the procedures that will be performed in this project. For personnel without prior relevant experience, state how they will be trained to work with biohazards in the laboratory, by whom that training is provided, and how it is determined that they are competent to conduct independent work with biohazards. Click or tap here to enter text.
  3. Has viewed the following biohazard CITI online training modules and successfully passed the corresponding quizzes (\*Required):

\*Initial Biosafety  \*Lab Chemical Safety  NIH rDNA Guidelines

OSHA Bloodborne Pathogens  Nanotechnology  Animal Biosafety

Select Agents, Biosecurity, and Bioterrorism  DURC

Name: Enter here Department: Enter here UM email: Enter here Title: Enter here

* 1. Describe the role this researcher will perform in this project: Click or tap here to enter text.
  2. Describe the researcher’s experience and qualifications related to the procedures that will be performed in this project. For personnel without prior relevant experience, state how they will be trained to work with biohazards in the laboratory, by whom that training is provided, and how it is determined that they are competent to conduct independent work with biohazards. Click or tap here to enter text.
  3. Has viewed the following biohazard CITI online training modules and successfully passed the corresponding quizzes (\*Required):

\*Initial Biosafety  \*Lab Chemical Safety  NIH rDNA Guidelines

OSHA Bloodborne Pathogens  Nanotechnology  Animal Biosafety

Select Agents, Biosecurity, and Bioterrorism  DURC

**Section 2: Description of research and facilities used (Required Section)**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| A. | In lay language, provide a brief description of your project, including the broad goals and potential benefits of research (do not provide a grant proposal). Provide definitions or explanations of technical terms and jargon:  Click or tap here to enter text. | | | | | | |
| B. | Will vertebrate animals be involved? | No |  | Yes |  | IACUC Number: |  |
| C. | Will non-vertebrate animals be involved? | No |  | Yes |  | Species: |  |
| D. | Will human subjects directly or indirectly (samples) be used? | No |  | Yes |  | IRB Number: |  |
| E. | Will plants be used? | No |  | Yes |  |  | |
| F. | Will you be shipping biological hazards outside of U.S.? | No |  | Yes |  | Which country: |  |

G. Location of facilities where biological agents are used for this project (See Example in Red):

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Name of Building or Field Plot** | **Room #(s)** | BSL  **(1-3)** | ABSL  **(1-3)** | BSL-P  **(1-3)** | **Species of Animals housed in these rooms**  **or location** | **Species of Plants housed in these rooms or location** |
| TCRC West | 219 | 2 | N/A | N/A | None | None |
| Enter here | Enter here | Enter here | Enter here | Enter here | Enter here | Enter here |
| Enter here | Enter here | Enter here | Enter here | Enter here | Enter here | Enter here |
| Enter here | Enter here | Enter here | Enter here | Enter here | Enter here | Enter here |

Additional rows may be added with the TAB key

|  |  |  |
| --- | --- | --- |
| Yes | No | **Infectious agents (animal, human, or plant) or Select agents and/or toxins;** If yes, complete **section 3.** |
|  |  |  |
| Yes | No | **Generating and handling recombinant or synthetic nucleic acids (r/sNA) or using cells, organisms and viruses containing such molecules;** If yes, complete **section 4.** |
|  |  |  |
| Yes | No | **Human or non-human primate blood, body fluids, cells, cell lines, and tissues;** If yes, complete **section 5**. |
|  |  |  |
| Yes | No | **Transgenic plants;** if yes, complete **sections 4 & 6.** |
|  |  |  |
| Yes | No | **Transgenic animals;** If yes, complete **sections 4 & 7.** |
|  |  |  |
| Yes | No | **Dual Use Research of Concern;** If yes, complete **section 8.** |
| Yes | No | **Nanomaterials;** If yes, complete **section 9.** |

Yes  No  Highly toxic chemical**,** **chemical carcinogens/mutagens and cytotoxic drugs**; if yes, complete **section 10**.

**Section 3: Infectious/Select agents and biological toxins:** YesNo

If Yes, expand and complete the sections below.

Select agents require registration with the Federal Select Agent Program (FSAP) administered by UM ORSP. Both the CDC and USDA APHIS oversee the program and approve research utilizing these agents. Additional information on Select Agents and Toxins can be found on the [Biosafety Website](https://safety.olemiss.edu/safety-programs/biological-safety/biological-safety-manual/) or the [FSAP](https://www.selectagents.gov/index.htm) (A list of excluded agents and toxins are found [here](https://www.selectagents.gov/sat/exclusions/index.htm)). Contact the IBC prior to submitting a registration.

**A. PLEASE CHECK THE BOXES BELOW INDICATING SELECT AGENTS AND TOXINS USED IN YOUR LABORATORY.**

**HHS Select Agents and Toxins**

*Abrin (over 1000mg)*

*Bacillus cereus* Biovar *anthracis*

Botulinum neurotoxins (over 1mg)

Botulinum neurotoxin producing species of *Clostridium*

Short, paralytic alpha conotoxins containing the following amino acid sequence X1CCX2PACGX3X4X5X6CX7 (over 100 mg)

*Coxiella burnetiid*

Crimean-Congo haemorrhagic fever virus

Diacetoxyscirpenol (over 10,000mg)

Eastern Equine encephalitis virus

Ebola viruses

*Francisella tularensis*

Lassa fever vírus

Lujo virus

Marburg virus

Mpox virus

Reconstructed 1918 influenza virus

Ricin (over 1000mg)

*Rickettsia prowazekii*

SARS-associated coronavirus (SARS-CoV)

SARS-CoV/SARS-CoV-2 chimeric viruses resulting from any deliberate manipulation of SARS-CoV-2 to incorporate nucleic acids coding for SARS-CoV virulence factors

Saxitoxin (over 500mg)

South American haemorrhagic fever viruses.

Chapare

Guanarito

Junin

Machupo

Sabia

Staphylococcal enterotoxins A,B,C,D,E subtypes (over 100mg)

T-2 toxin (over 10,000mg)

Tetrodotoxin (over 500mg)

Tick-borne encephalitis complex (flavi) viruses

Far Eastern subtype

Siberian subtype

Kyasanur Forest disease virus

Omsk hemorrhagic fever virus

Variola major virus (Smallpox virus)

Variola minor virus (Alastrim)

*Yersinia pestis*

**Overlap Select Agents and Toxins**

*Bacillus anthracis*

*Bacillus anthracis* Pasteur strain

*Brucella abortus*

*Brucella melitensis*

*Brucella suis*

*Burkholderia mallei*

*Burkholderia pseudomallei*

Hendra virus

Nipah Virus

Rift Valley fever virus

Venezuelan equine encephalitis virus

**USDA Select Agents and Toxins**

African horse sickness virus

African swine fever virus

Avian influenza virus

Classical swine fever virus

Foot and mouth disease virus

Goat pox virus

Lumpy skin disease virus

*Mycoplasma capricolum*

*Mycoplasma mycoides*

Newcastle disease virus

Peste Des Petits Ruminants virus

Rinderpest virus

Sheep pox virus

Swine vesicular disease virus

**USDA Plant Protection and Quarantine (PPQ) Select Agents and Toxins**

*Coniothyrium glycines (formerly Phoma glycinicola and Pyrenochaeta glycines)*

*Peronosclerospora philippinensis (Peronosclerospora sacchari)*

*Ralstonia solanacearum*

*Rathayibacter toxicus*

*Schlerophthora rayssiae*

Synchytrium endobioticum

*Xanthomonas oryzae*

1. **List all Select and Non-Select Agents and Toxins (additional rows may be added with the TAB key).**

For definition of BSL classifications refer to Biosafety in Microbiological and Biomedical Laboratories ([BMBL](https://www.cdc.gov/labs/BMBL.html)) or the [NIH Guidelines](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf) for use of r/sNA.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Infectious Agent** | **Toxin** | Known Hazard to: | **Human Vaccines Available** | **Treatment Available** | **BSL Level** | | |
| 1 | 2 | 3 |
| Enter here | Enter here | **Human  Animal  Plant** | **Yes  No** | **Yes  No** |  |  |  |
| Enter here | Enter here | **Human  Animal  Plant** | **Yes  No** | **Yes  No** |  |  |  |
| Enter here | Enter here | **Human  Animal  Plant** | **Yes  No** | **Yes  No** |  |  |  |
| Enter here | Enter here | **Human  Animal  Plant** | **Yes  No** | **Yes  No** |  |  |  |
| Enter here | Enter here | **Human  Animal  Plant** | **Yes  No** | **Yes  No** |  |  |  |
| Enter here | Enter here | **Human  Animal  Plant** | **Yes  No** | **Yes  No** |  |  |  |

1. **Briefly answer the following questions (if applicable):**
   1. Briefly describe the research methods, microbiological practices, and lab procedures with the infectious agents and/or toxins in lay language. Click or tap here to enter text.
   2. 2. What is the source of the agent, toxin, or

* potentially biohazardous material? Click or tap here to enter text.

3. What is your assessment of the biohazardous potential? Include personal protective equipment and vaccines that will be required (if applicable). Click or tap here to enter text.

4. What containment procedures will be used when storing and transporting agents within and between facilities? Provide an example of the double containment used when transporting agents outside of the primary laboratory facility. Click or tap here to enter text.

5. What is the method of terminal inactivation of the biological agent (autoclave, chemical inactivation, compost, steam sterilization technology-STI, incineration)? Click or tap here to enter text.

6. What is the disposal method for waste including inoculated animals, animal bedding and waste, or plants? Click or tap here to enter text.

7. Describe the procedure(s) for an accidental spill or exposure to personnel. Click or tap here to enter text.

8. List all materials that require federal permits and include copies of these permits with this application. Click or tap here to enter text.

**Section 4: Recombinant or Synthetic Nucleic Acid (r/sNA) molecules** YesNo

If Yes, expand and complete the sections below.

1. Briefly answer the following questions:
   1. Briefly describe the research methods and laboratory procedures with the recombinant or synthetic nucleic acid molecules, in lay language. Click or tap here to enter text.
   2. What is your assessment of the biohazardous potential? Include personal protective equipment. Click or tap here to enter text.
   3. What containment procedures will be used when storing and transporting recombinant or synthetic nucleic acid molecules within and between facilities? Provide an example of the double containment used when transporting biohazards outside of the primary laboratory facility. Click or tap here to enter text.
   4. What is the method of terminal inactivation of the biological agent (autoclave, chemical inactivation, compost, steam sterilization technology-STI, incineration)? Click or tap here to enter text.
   5. What is the disposal method for waste including inoculated animals, animal bedding and waste, or plants? Click or tap here to enter text.
   6. Describe the procedure(s) for an accidental spill or exposure to personnel. Click or tap here to enter text.
2. Are you working with recombinant or synthetic nucleic acids or recombinant organisms? Yes  No

If yes, complete the questions below. If no, skip to section 4B.

1. Source of nucleic acid (e.g. species). Click or tap here to enter text.
2. Nature of the inserted nucleic acid sequences. Click or tap here to enter text.
3. Host(s) and vector(s) to be used. Click or tap here to enter text.
4. Will an attempt be made to obtain expression of a foreign gene? If so, indicate the protein that will be produced. Click or tap here to enter text.
5. What is the appropriate biosafety level? Click or tap here to enter text.
6. What are the containment conditions? Click or tap here to enter text.
7. Are you working with CRISPR or similar technology (TALENs, Zinc Fingers, etc.)? Yes  No

If yes, complete the questions below. If no, skip to section 4C.

1. Which organism(s) is being modified? Click or tap here to enter text.
2. Is the gene being knocked-in or -out? Click or tap here to enter text.
3. Is the work in cell culture? Click or tap here to enter text.
   * If yes, please list the cell lines. Click or tap here to enter text.
4. Is the work in whole organism(s)? Yes  No 
   * If yes, please list the whole organism(s). Click or tap here to enter text.
5. What is the function of the gene(s) being modified? Click or tap here to enter text.
6. What will be the function of the gene(s) once modified? Click or tap here to enter text.

**CRISPR Information: Discuss the desired effect of gene editing on animals or cell line. You must address the potential effects due to accidental worker exposure. If unknown, state that. Points to consider are:**

1. Are the guide RNA gene and the Cas9 gene physically linked on the same piece of DNA? Click or tap here to enter text.
   * If yes, please describe. Click or tap here to enter text.
2. Is the guide RNA sequence specific to animals, humans, or could it affect both? Click or tap here to enter text.
   * Describe any similarity between human and animal guide sequences. Click or tap here to enter text.
3. What is known about off-target effects with the system you are using? Click or tap here to enter text.
4. How much genotype change (dose) is needed for a physical effect? Click or tap here to enter text.
5. How does route of exposure affect outcome? Click or tap here to enter text.
6. Can the mutation potentially drive through a population? Click or tap here to enter text.
7. What should be done in the event of an accidental exposure (e.g. needle stick) to the gene editing system? Click or tap here to enter text.
8. What safety precautions should be in place for this work? Click or tap here to enter text.
9. Are you generating Gene Drive Modified Organisms (GDMOs)? Yes  No

## If yes, complete the questions below. If no, skip to section 5.

1. What is the goal of this research involving GDMOs? Click or tap here to enter text.
2. Which organism(s) is being modified? Click or tap here to enter text.
3. What is the function of the gene(s) being modified? Click or tap here to enter text.
4. What will be the function of the gene(s) once modified? Click or tap here to enter text.
5. What is the source of the genetic material (sequences of transgenes) in the construct?
6. What is the modification to the construct?
7. What are the benefits? Click or tap here to enter text.
8. What are potential risks involved (to the environment and lab personnel)? Click or tap here to enter text.
9. Will the frequency of inheritance of the genetic construct remain constant from one generation to the next? Click or tap here to enter text.
10. What is the possibility for gene flow to non-target species? Click or tap here to enter text.
11. What are the possible consequences of escaping into the environment?
12. What is the potential ability of the gene drive to spread or persist in local populations?
13. How reliable are molecular markers, such as adding a unique eye color, intended to facilitate the monitoring of gene-drive modified organisms after they have been released to the environment? Click or tap here to enter text.
14. What mitigation strategies are in place for unintended, harmful effects and how can the efficacy of such an approach be evaluated? Click or tap here to enter text.

**Section 5: Human or Non-human Primate Blood, body fluids, cells, cell-lines, and tissues** YesNo

If Yes, expand and complete the sections below.

Human and non-human primate blood, body fluids, cells, and tissues must be treated as though containing infectious agents.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 1. |  | **Blood** |  |  | **Vendor/Collaborator:** | Enter here |
|  |  |  |  |  |  |  |
| 2. |  | **Body fluids** | **List type:** | Enter here | **Vendor/Collaborator:** | Enter here |
|  |  |  |  |  |  |  |
| 3. |  | **Cells/tissues** | **List type:** | Enter here | **Vendor/Collaborator:** | Enter here |
|  |  |  |  |  |  |  |
| 4. |  | **Primary Cell Lines** | **List type:** | Enter here | **Vendor/Collaborator:** | Enter here |
|  |  |  |  |  |  |  |
| 5. |  | **Established Cell lines** | **List type:** | Enter here | **Vendor/Collaborator:** | Enter here |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 6. | Do any of the cells, tissues, or cell lines have characterized agents? |  | Yes |  | No | **If Yes, Fill out Section 3** |

|  |  |
| --- | --- |
| 7.  8.  9.  10.  11. | Briefly describe the research methods and lab procedures (e.g. sample collection, cell culture, DNA, RNA, or protein isolation, flow cytometry, etc.) with the human or primate blood, body fluids, cells, tissues in lay language. Click or tap here to enter text.  Identify known and potential hazards associated with this material (e.g. bloodborne pathogens, known or potential disease states associated with the material, the use of sharps, hazardous materials, procedures that may aerosolize the materials, etc.). Specifically describe safe practices, equipment, facilities, and training used to protect staff from hazards listed above. Click or tap here to enter text.  What containment procedures will be used when storing and transporting agents within and between facilities? Provide an example of the double containment used when transporting agents outside of the primary laboratory facility. Click or tap here to enter text.  Specifically describe methods of inactivation and disposal of the material and any associated contaminated materials generated. Click or tap here to enter text.  In cases of accidental spill or exposure, specifically describe the protocol that will be employed, decontamination agents, equipment to be used (i.e. autoclave, biohazard bag, disinfectants, etc.), where to seek medical help in the event of a human exposure, and where to file a work-related accident report. Click or tap here to enter text. |
|  |  |

\* Please note: Use and/or collection of human blood, body fluids, cells, or tissues may require human subjects’ approval from the UM [IRB](http://www.irb.wsu.edu/).

**Section 6: Transgenic plants** YesNo

If Yes, expand and complete the sections below.

The [NIH Guidelines](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf) require that transgenic plant activities require IBC review prior to initiation of the research. Please refer to the NIH Guidelines or contact IBC for additional information

**A. *Please check Yes or No for each of the following categories and fill in appropriate boxes***

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Yes |  | No | 1. | Transgenic whole plants will be maintained in the laboratory, greenhouse, or growth chamber. | | | | | | | | | | | | | | | | | | | |
|  |  |  |  |  | | | | | | | | | | | | | | | | | | | |
| Yes |  | No | 2. | Transgenic whole plants will be introduced into the field. | | | | | | | | | | | | | | | | | | | |
|  | | | | |  | | | | | | | | | | | | | | | | | |
| a. | | | | | If a pharmaceutical or bioactive industrial compound will be synthesized in a food or feed crop, state the reason for choosing that crop: | | | | | | | | | | | | | | | | | |
|  | | Click or tap here to enter text. | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | |
| b. | | | | | Describe information gained from lab and growth chamber or greenhouse experiments that would be relevant to assessing potential risks from field tests: | | | | | | | | | | | | | | | | | |
| Click or tap here to enter text. | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | |
| c. | | | | | Describe procedures to monitor for and eliminate any volunteer plants:  Click or tap here to enter text. | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | |
| d. | | | | | How close is the field planting to other plants where gene flow or cross pollination could occur? | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | |
|  | Less than 100 feet | | | | |  | | Less than one mile | | | |  | | | | |  | | |
|  | | | | |  | | |  |  | | |  | | | | |  | | | | | |
|  | | | | |  | Less than 100 yards | | | | |  | | Greater than one mile | | | | | |  | | |  | | |
|  | | | | |  | | |  |  |  | | | | | | | | | | | | |
|  | | | | |  | Not applicable | | | | |  | | Explain: | | Click or tap here to enter text. | | | | | | | | | | |
|  | | | | |  | | |  |  |  | | | | | | | | | | | | |
| e. | | | | | Have bordering farms been made aware of the transgenic field release? | | | | | | | | | Yes | | | | No | | |  | |
|  | | | | |  | | | | | | | | |  | |  | |  | |  |  | |
| f. | | | | | I agree to adhere to all federal guidelines as outlined in the attached copy of the APHIS approval/permit | | | | | | | | | Yes | | | | No | | |  | |
|  | |  | |  | |  |  | |
|  | | | | |  | | | | | | | | |  | |  | |  | |  |  | |
| g. | | | | | A planting map with GPS coordinates and bordering field planting information has been attached. | | | | | | | | | Yes | | | | No | | |  | |
|  | |  | |  | |  |  | |
|  | | | | |  | | | | | | | | |  | |  | |  | |  |  | |
| Yes |  | No | 3. | Is the recombinant plant a noxious weed? | | | | | | | | | | | | | | | | | | | |
|  |  |  |  |  | | | | | | | | | | | | | | | | | | | |
| Yes |  | No | 4. | Can the recombinant plant interbreed with weeds in the area? | | | | | | | | | | | | | | | | | | | |
|  |  |  |  |  | | | | | | | | | | | | | | | | | | | |
| Yes |  | No | 5. | Does the recombinant plant have recognized potential for detrimental environmental impact on managed or natural ecosystems? | | | | | | | | | | | | | | | | | | | |
|  |  |  |
|  |  |  |  |  | | | | | | | | | | | | | | | | | | | |
| Yes |  | No | 6. | Does the recombinant DNA work contain a complete genome of a non-exotic infectious agent? | | | | | | | | | | | | | | | | | | | |
|  |  |  |  |  | | | | | | | | | | | | | | | | | | | |
| Yes |  | No | 7. | Does the recombinant DNA work contain the genome of an exotic infectious agent? | | | | | | | | | | | | | | | | | | | |
|  |  |  |  |  | | | | | | | | | | | | | | | | | | | |
| Yes |  | No | 8. | Could this work reconstitute the genome of an infectious agent in a plant? | | | | | | | | | | | | | | | | | | | |
|  |  |  |  |  | | | | | | | | | | | | | | | | | | | |
| Yes |  | No | 9. | Does this work involve exotic infectious agents with potentially detrimental environmental impact? | | | | | | | | | | | | | | | | | | | |
|  |  |  |  |  | | | | | | | | | | | | | | | | | | | |
| Yes |  | No | 10 | Contains an exogenous toxin? If yes, please describe: | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | |

**B. Please complete the questions below:**

1. Briefly describe the research methods, practices, and lab procedures with the transgenic plants in lay language. Click or tap here to enter text.
2. What is your assessment of the biohazardous potential? Include personal protective equipment and vaccines that will be required (if applicable). Click or tap here to enter text.
3. What containment procedures will be used when storing and transporting transgenic plants within and between facilities? Provide an example of the double containment used when transporting agents outside of the primary laboratory facility. Click or tap here to enter text.
4. What is the method of terminal inactivation of the biological agent (autoclave, chemical inactivation, compost, desiccation, chopping/mincing, steam sterilization technology-STI, incineration)? Click or tap here to enter text.
5. What is the disposal method for waste including plants? Click or tap here to enter text.
6. Describe the procedure(s) for an accidental spill or exposure to personnel. Click or tap here to enter text.
7. List all materials that require federal permits and include copies of these permits with this application. Click or tap here to enter text.

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**Section 7: Transgenic animals** YesNo

If Yes, expand and complete the sections below.

**A. This section is to be completed for any transgenic vertebrate or non-vertebrate animals.**

**Exception:** Projects involving the purchase, transfer, and use of transgenic rodents in BSL-1 experiments are not required to fill out this form. Breeding of BSL-1 rodent colonies within the same genetic lineage is also exempt if:

* Both parental rodents can be housed under BSL-1 containment; **and** neither parental transgenic rodent contains either of the following genetic modifications:
  + Incorporation of more than one-half of the genome of a eukaryotic virus from a single family of viruses; **or**
  + Incorporation of a transgene that is under the control of a gammaretroviral terminal repeat (LTR); **and**
* The transgenic rodent that results from this breeding is not expected to contain more than one-half of an exogenous viral genome from a single family of viruses.

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**This research utilizes only rodents that meet this exception.**

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**This exception does not apply to the animals involved in this research.**

**B. For transgenic animal research (not excepted as described above) complete the following section:**

1. Source of animal: Click or tap here to enter text.
2. If breeding BSL-1 rodent colonies with other genetic lines, describe the genetic make-up of both lineages that will be used for breeding: Click or tap here to enter text.
3. Briefly describe the research methods, practices, and lab procedures with the transgenic animals in lay language. Click or tap here to enter text.
4. What is your assessment of the biohazardous potential? Include personal protective equipment and vaccines that will be required (if applicable). Click or tap here to enter text.
5. What containment procedures will be used when storing and transporting transgenic animals within and between facilities? Provide an example of the double containment used when transporting agents outside of the primary laboratory facility. Click or tap here to enter text.
6. Animal decontamination upon termination of experiment (composting, Steam Sterilization Technology-STI, incineration, etc.): Click or tap here to enter text.
7. What is the disposal method for waste including inoculated animals, animal bedding and waste? Click or tap here to enter text.
8. Describe the procedure(s) for an accidental spill or exposure to personnel. Click or tap here to enter text.

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| **C.** | **Briefly list all transgenic animals utilized in this research:** | | |

**Section 8: Dual Use Research of Concern (DURC) Form:** YesNo

If Yes, expand and complete the sections below.

|  |  |  |
| --- | --- | --- |
| * Avian influenza virus (highly pathogenic) | * Ebola virus | * Renderpest virus |
| * *Bacillus anthracis* | * Foot-and-mouth disease virus | * Toxin-producing strains of *Clostridium botulinum* |
| * Botulinum neurotoxin | * *Francisella tularensis* | * Variola major virus |
| * *Burkholderia pseudomallei* | * Marburg virus | * Variola minor virus |
| * *Burkholderia mallei* | * Reconstructed 1918 influenza virus | * *Yersinia pestis* |

Dual use potential is defined as the potential for research projects with a beneficial purpose to provide knowledge, products or technologies that could be directly misapplied to pose a threat to public health and safety, agricultural crops and other plants, animals, the environment, or material (<https://osp.od.nih.gov/biotechnology/dual-use-research-of-concern/>). Consider whether your research is reasonably anticipated to do any of the following based on current understanding and comment on aspects of your research, if any, with potential for dual use. If not applicable, state “N/A”

* Enhance the harmful consequences of a biological agent or toxin. Click or tap here to enter text.
* Disrupt immunity or the effectiveness of an immunization without clinical and/or agricultural justification. Click or tap here to enter text.
* Confer to a biological agent or toxin, resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitate their ability to evade detection methodologies. Click or tap here to enter text.
* Increase the stability, transmissibility, or the ability to disseminate a biological agent or toxin. Click or tap here to enter text.
* Alter the host range or tropism of a biological agent or toxin. Click or tap here to enter text.
* Enhance the susceptibility of a host population to the pathogenic consequences of an agent or toxin. Click or tap here to enter text.
* Generate a novel pathogenic agent or toxin or reconstitute an eradicated or extinct biological agent. Click or tap here to enter text.
* Provide other knowledge, products, or technologies that could be directly misapplied to pose a threat to public health and safety, agricultural crops and other plants, animals, the environment, or material. Click or tap here to enter text.

**Section 9: Nanoparticles (particles that are ≤1000 nanometers)** YesNo

If Yes, expand and complete the sections below.

* + - 1. Describe the nanoparticles and how they will be utilized. Click or tap here to enter text.
      2. What is the biologically active or cell-modifying molecule(s) that will be used?
      3. Complete the table:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Chemical Name of Nanoparticle** | **Will You Be Making Nanoparticles for Use?** | **Physical Form** | **Administered to Animals (specify species)?** | **Route of Administration** |
| Enter here | Choose an item. | Choose an item. | Enter here | Enter here |
| Enter here | Choose an item. | Choose an item. | Enter here | Enter here |
| Enter here | Choose an item. | Choose an item. | Enter here | Enter here |
| Enter here | Choose an item. | Choose an item. | Enter here | Enter here |
| Enter here | Choose an item. | Choose an item. | Enter here | Enter here |

3. Provide a risk assessment of the nanoparticle(s) that will be used. Include any known or potential toxicities of the nanoparticle and/or the parent compound. Click or tap here to enter text.

4. List potential route(s) of exposure and list engineering controls and personal protective equipment that will be used when handling nanomaterials. Click or tap here to enter text.

5. Will any procedures that may cause aerosolization be performed (i.e. vortexing, centrifugation, pouring, pipetting, etc.)? If so, describe practices that will be used to minimize exposure while performing these procedures. Click or tap here to enter text.

6. What containment procedures will be used when storing and transporting nanomaterials within and between facilities? Provide an example of the double containment used when transporting nanomaterials outside of the primary laboratory facility. Click or tap here to enter text.

7. Describe how waste will be disposed of. Click or tap here to enter text.

8. List the procedures to be taken in case of an accidental exposure or spill. Click or tap here to enter text.

**Section 10: Chemical carcinogens/mutagens and cytotoxic drugs** YesNo

If Yes, expand and complete the sections below.

The National Institute for Occupational Safety and Health (NIOSH) has compiled a list of hazardous drugs that have been identified as a carcinogenic, developmental, reproductive, genotoxic, or other health hazard in humans, animal models, or in vitro systems (<https://www.cdc.gov/niosh/docs/2016-161/pdfs/2016-161.pdf>; with updated tables in <https://www.cdc.gov/niosh/docket/review/docket233c/pdfs/DRAFT-NIOSH-Hazardous-Drugs-List-2020.pdf>).

1. Describe the hazardous drug(s) and how they will be utilized. Click or tap here to enter text.
2. Provide a risk assessment of the hazardous drug(s) that will be used. Include the LD50 (include citation) any known or potential toxicities of the hazardous drug(s). Click or tap here to enter text.
3. List potential routes of exposure and list engineering controls and personal protective equipment that will be used. Click or tap here to enter text.
4. What containment procedures will be used when storing and transporting hazardous chemicals(s) within and between facilities? Provide an example of the double containment used when transporting hazardous chemical(s) outside of the primary laboratory facility. Click or tap here to enter text.
5. Describe how waste will be disposed of. Click or tap here to enter text.
6. List procedures to be taken in case of an accidental exposure or spills. Click or tap here to enter text.