Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Title of Project: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Protocol #: \_\_\_\_\_\_\_\_\_\_ (leave blank and this will be filled in by the IBC)

Funding Source: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ RTT grant/proposal #: \_\_\_\_\_\_\_\_\_\_\_\_

Give the names of all individuals who will work with you on this project. \*\*If additional space is needed, submit a separate word document.\*\*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Name** | **Department** | **Email Address** | **Faculty/Student, etc.** | **Roles/Responsibilities for this project** |
|   |   |   |   |   |
|   |   |   |   |   |
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**Study Information:** *Please give a brief description (100 words or less) of the activity planned. Use phrasing and words that would be easily understood by non-scientists having no knowledge of your project. Avoid using abbreviations, jargon, and technical vocabulary or phrases.*

**Identification of Biohazards:** *Check all that apply*

[ ] Recombinant or synthetic nucleic acid molecules (eg: rDNA, siRNA, transgenic

animals, transgenic plants, etc.)

[ ]  Infectious Agents (eg: bacteria, protozoa, fungi, prions, or viruses pathogenic to

plants, humans, or animals)

[ ]  Toxins

[ ]  Tumorigenic Material (See IBC website to determine what qualifies as

"tumorigenic": https://www.k-state.edu/comply/ibc/faqs)

[ ] Human Blood, Tissue, or Bodily Fluids

[ ] Human Cell Lines

[ ] Select Agents: the complete list from the Federal Select Agent Program is found

here: <https://www.selectagents.gov/sat/list.htm> .

**Biohazard Agent Source(s):**

Do you currently possess the biohazard agent(s) for this work?

[ ]  Yes

[ ]  No

Provide the name and source of the agent(s)/material(s) (e.g. ATCC) that will be used in this activity. If you currently possess the agent, please indicate.

**State the Objectives of the project:**

**Describe the Scientific Plan:**

**My proposed activity involves the use or creation of recombinant or synthetic nucleic acid (NA) molecules:**

[ ]  Yes

[ ]  No

If yes:

From what organism is the cloned NA derived? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

What is the risk group (ex. RG2) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Was the NA amplified from an infectious organism in the laboratory [ ]  No [ ]  Yes

* + If yes, which infectious organism: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

What is the nature of the inserted NA (toxin gene, anonymous marker, kinase gene, oncogene, etc.)? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Are you using a gene editing technology? [ ]  No [ ]  Yes

If so, specific the type (CRISPR/Cas9, Zinc Finger Nuclease, TALENs, etc.):

Describe all hosts to be used for the cloned NA and the expression vectors to be used for cloning. Give the genotypes of the host bacteria, fungi, insects, etc. and the names of vectors. Please describe the relevant components of all vectors other than standard ones such as pUC18/19 or pBluescript.

Will a gene product be expressed from the cloned NA? [ ]  No [ ]  Yes

Please evaluate the bio risk (if any) of working with this product:

Are you proposing to grow cultures of recombinant or synthetic NA of more than 10 liters in a single experiment? [ ]  No [ ]  Yes

Specify the rationale for the large amounts:

Will your activity involve the use or creation of transgenic plants, arthropods, or animals?

[ ]  No [ ]  Yes

Provide information on: strains, genetic traits, and the intended use:

Please list any biological agents that are modified/will be modified with recombinant nucleic acid technology. Please include these agents and their characteristics.

**Guidelines Section and Biosafety Level:**

*Based on your Risk Assessment for the proposed activities, provide the following*

*information using the NIH guidelines for recombinant or synthetic nucleic acid*

*molecules at:* *<https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf>*

Please provide the applicable section of the NIH Guidelines:

**Animals:**

Will animals be used? [ ]  No [ ]  Yes

*(If yes, a protocol must be submitted and approved by the WSU IACUC prior to the use of animals.)*

Do you already have a protocol submitted? [ ]  No [ ]  Yes

If yes, what is the IACUC protocol number? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Non-Recombinant Biohazardous Materials:**

Does the activity involve agents (eg: bacteria, protozoa, fungi, prions, or viruses) pathogenic to plants, humans, or animals, toxins, tumorigenic materials, or human materials? [ ]  No [ ]  Yes

**Guidelines Section and Biosafety Level:**

*Based on your Risk Assessment for the infectious agent or tumorigenic material, provide the following information using the BMBL 6th edition at*

*https://www.cdc.gov/labs/pdf/SF\_\_19\_308133-A\_BMBL6\_00-BOOK-WEB-final-3.pdf or the ORICS containment level flow chart*

Display Agent Specific Biosafety Table

|  |  |  |  |
| --- | --- | --- | --- |
| **Agent (Genus and Species)** | **Applicable BMBL Guidelines** | **Agent Risk Group** | **Biosafety Level** |
|   |   |   |   |
|   |   |   |   |
|   |   |   |   |
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**Provide Agent Characteristics:**

What is the host of this pathogen?

Will your work involve biological materials derived from humans, including all human cell lines, blood, or tissue? [ ]  No [ ]  Yes

Will your staff members be trained on the universal precautions for handling these types of materials?

*(Further information can be found here:* [*https://www.cdc.gov/niosh/healthcare/risk-factors/bloodborne-infectious-diseases.html?CDC\_AAref\_Val=https://www.cdc.gov/niosh/topics/bbp/universal.html*](https://www.cdc.gov/niosh/healthcare/risk-factors/bloodborne-infectious-diseases.html?CDC_AAref_Val=https://www.cdc.gov/niosh/topics/bbp/universal.html) *)*

*To prevent contracting Hepatitis B from human blood or other potentially infectious human materials, all research team members must be offered the Hepatitis B vaccination.*

*Individuals who are already vaccinated or do not wish to receive the vaccine will be asked to sign a declination form. A sample declination form can be found here: Hepatitis B Vaccine Declination Form.*

*Information regarding Hepatitis B and the vaccine is found here:* [*https://www.cdc.gov/hepatitis/hbv/index.htm*](https://www.cdc.gov/hepatitis/hbv/index.htm)

Will Lentivirus Viral Vectors (LVVs) be used in this protocol? [ ]  No [ ]  Yes

*\*\*if yes, more information will be required\*\**

**Vertebrate Animals:**

Will vertebrate animals be used: [ ]  No [ ]  Yes

What animal species will be used: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

What is the status of the IACUC Protocol? [ ]  Pending [ ]  In Process [ ] Approved

How will the agent be administered to the animals (e.g. IV injection, oral, topical)?

Will the animals be shedding the agent? [ ]  No [ ]  Yes

Provide information on how the agent is shed, the expected duration of the shedding, and how long the agent will remain viable in the environment.

Will the animals be necropsied? [ ]  No [ ]  Yes

Based on your risk assessment, what is the most appropriate ABSL for this research?

*Animal Biological Safety Levels (ABSLs) are based on Section V of the Biosafety in Microbiological and Biomedical Laboratories (BMBL):*

*https://www.cdc.gov/labs/pdf/SF\_\_19\_308133-A\_BMBL6\_00-BOOK-WEB-final-3.pdf*

**Arthropod Usage:**

My activity involves arthropods? [ ]  No [ ]  Yes \*\*if yes, more information will be required\*\*

**Plant Usage:**

My activity involves plants? [ ]  No [ ]  Yes \*\*if yes, more information will be required\*\*

**Human Subjects:**

Does your activity involve the participation of human research subjects? [ ]  No [ ]  Yes

*\*\*if yes, a protocol must be submitted and approved by the WSU IRB prior to the involvement of human subjects.\*\**

What is the status of the IRB Protocol? [ ] Pending [ ]  In Process [ ] Approved

What is the IRB Protocol number? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Experiment Location:**

Provide the laboratory locations where the experiments will be conducted:

**Agent Manipulations:**

Describe the types of manipulations planned.

Describe the containment conditions you will implement in the laboratory.

*(For examples see page 32 of the BMBL 6th Edition: https://www.cdc.gov/labs/pdf/SF\_\_19\_308133-A\_BMBL6\_00-BOOKWEB-final-3.pdf)*

Will you be using a biosafety cabinet (BSC) or other containment device? [ ]  No [ ]  Yes

*(Information describing BSC can be found at: http://www.phacaspc.gc.ca/publicat/lbg-ldmbl-04/ch9-eng.php)*

Based on your risk assessment, what is the most appropriate BSL for this research?

*Biological Safety Levels (BSLs) are based on Sections I-IV of the Biosafety in Microbiological and Biomedical Laboratories(BMBLs):*

[*https://www.cdc.gov/labs/pdf/SF\_\_19\_308133-A\_BMBL6\_00-BOOK-WEB-final-3.pdf*](https://www.cdc.gov/labs/pdf/SF__19_308133-A_BMBL6_00-BOOK-WEB-final-3.pdf)