UNIVERSITY OF OREGON

Biological Research Registration Form

The University of Oregon requires Institutional Biosafety Committee review and approval of research involving recombinant or synthetic nucleic acids (rsNA), organisms in Risk Group 2 or higher, biological toxins, select agents, and non-human primate materials. Please complete this registration form and submit to the Biosafety Officer for initial review. Separate forms do not need to be completed for individual grants and may broadly cover several aspects of work.

SECTION I

Principal Investigator (PI):	**Registration #** (issued by EHS)**:**
College:	**Department:**
Phone Number:	**Email:**
Project Title:	
Other personnel working on project:	
Lab Building(s) and Room Number(s):	
Please list all applicable UO Sponsored Projects EPCS Record #s or Banner Grant #s:	
Institutional Animal Care & Use Committee (IACUC) approval number(s), if applicable:	

SECTION II: Please complete applicable questions as they pertains to the work you are conducting.

1. Recombinant or synthetic nucleic acids (rsNA) in *E.coli K-12* only

☐ *CHECK IF THIS SECTION IS NOT APPLICABLE*

a. Gene(s) encoded by inserted DNA: _____
b. Biological origin of inserted DNA: _____
c. Will inserted gene(s) be expressed in the host bacterium? ☐ Yes ☐ No
   If yes, what are the gene product effects (toxicity, physiological activity, oncogenic potential, or ability to alter cell cycle): _____
d. Vectors: _____
e. List antibiotic resistance genes contained on these vectors: _____
f. Do experiments involve large scale (>10 liters in one container) culture? ☐ Yes ☐ No
g. Do experiments involve cloning toxin genes? ☐ Yes ☐ No
   If yes, the Name of toxin: _____
h. Do experiments involve transfer of antibiotic resistance gene in addition to those contained in the vectors? ☐ Yes ☐ No
   If yes, the Name of antibiotic resistance gene: _____

2. Recombinant or synthetic nucleic acids (rsNA) in bacterial hosts other than E.coli K-12

☐ *CHECK IF THIS SECTION IS NOT APPLICABLE*

a. List the host species: _____
b. Genes encoded by inserted DNA: _____
c. Biological origin of inserted DNA: _____
d. Will inserted gene(s) be expressed? ☐ Yes ☐ No
   If yes, what are the gene product effects (e.g., toxicity, physiological activity, oncogenic potential, ability to alter cell cycle): _____
e. Vectors: _____
f. List antibiotic resistance genes contained on these vectors: _____
g. If the host is a human or animal pathogen, are any of the antibiotics listed above used to treat the disease in humans or animals: ☐ Yes ☐ No
   If yes, are any of the antibiotics used to treat the disease in any patient population? ☐ Yes ☐ No
   If yes, are any of the antibiotics used to treat the disease in other countries? ☐ Yes ☐ No
   If yes, list antibiotics that can be used to treat an infection with this microorganism, taking into consideration the inserted and naturally-occurring drug resistance genes: _____
h. Do experiments involve large scale (> 10 L in one container) culture? ☐ Yes ☐ No
i. Do experiments involve cloning biological toxin gene? ☐ Yes ☐ No
   If yes, name of toxin: _____
j. Do experiments involve transfer of an antibiotic resistance gene into the host in addition to those contained in the vectors? ☐ Yes ☐ No
   If yes, list the name of antibiotic resistance gene: _____

3. Recombinant or synthetic nucleic acids (rsNA) in lower eukaryotic hosts (e.g., parasites, fungi, algae)

☐ *CHECK IF THIS SECTION IS NOT APPLICABLE*

a. Name of host organism: _____
b. Gene(s) encoded by inserted DNA: _____
c. Biological origin of inserted DNA: _____
d. Vectors: _____
e. Will inserted gene(s) be expressed? ☐ Yes ☐ No
   If yes, what are the gene product effects (e.g., toxicity, physiological activity, oncogenic potential, ability to alter cell cycle): _____

4. Recombinant or synthetic nucleic acids (rsNA) in cell culture

☐ *CHECK IF THIS SECTION IS NOT APPLICABLE*

a. Tissue culture cell lines(s) name: _____
b. Source (species) of cell cultures: _____
c. Gene(s) encoded by inserted DNA: _____
d. Biological origin of inserted DNA: _____
e. Vectors: _____
f. Does vector contains > 2/3 of eukaryotic viral genome? ☐ Yes ☐ No
   If yes, name of virus: _____
g. Recombinant virus constructed? ☐ Yes ☐ No
   If yes, Name of virus: _____
   If yes, Name of transgene: _____
h. Reassortant virus constructed? ☐ Yes ☐ No
   If yes, describe reassortant virus in Overview section.
i. Packaging cell line used? ☐ Yes ☐ No
   If yes, packaging cell line name: _____
   If yes, virus produced is: _____
j. Defective virus with helper virus? ☐ Yes ☐ No
   If yes, helper virus: _____
k. Will inserted gene(s) be expressed? ☐ Yes ☐ No
   If yes, what are the gene product effects (toxicity, physiological activity, oncogenic potential, or ability to alter cell cycle): _____

5. Use of lentiviral vectors

☐ *CHECK IF THIS SECTION IS NOT APPLICABLE*

a. Is the vector HIV-1 based? ☐ Yes ☐ No
b. What is the transgene? _____
c. Does the transgene have oncogenic potential? ☐ Yes ☐ No
d. How many plasmids are used in the packaging system? _____
e. Has expression of TAT been deleted? ☐ Yes ☐ No
f. Is the HIV envelope gene present in the packaging system: ☐ Yes ☐ No
g. If the HIV envelope gene has been replaced, does the new envelope protein broaden the host cell and tissue tropism of the lentivirus? ☐ Yes ☐ No
h. If animals are involved, is lentivirus injected into the animal? ☐ Yes ☐ No
   Is the animal engrafted with transduced cells? ☐ Yes ☐ No

6. Generation of transgenic animals (including knockouts) by embryo injection

☐ *CHECK IF THIS SECTION IS NOT APPLICABLE*

a. Species of animal: _____
b. Gene or sequence injected: _____
c. Biological origin of inserted DNA: _____
d. What are the anticipated effects of inserted DNA (e.g. toxicity, physiological activity, oncogenic potential, ability to alter cell cycle): _____
e. Describe the precautions that will be taken to minimize the possibility that animals could escape confinement: _____
f. Describe the effect on the wild population if an animal were to escape and mate with wild-type:
   _____

7. Generation of transgenic animals by breeding

☐ *CHECK IF THIS SECTION IS NOT APPLICABLE*

a. Species of animal: _____

b. Are two different transgenic/knockout animal strains bred to create a new strain? ☐ Yes ☐ No

c. Is a transgenic (or knockout) animal strain being bred to a non-transgenic strain? ☐ Yes ☐ No

d. Does either transgenic parent contain a transgene under the control of a gamma-retroviral long terminal repeat (LTR)? ☐ Yes ☐ No

e. Does either transgenic parent contain more than 50% of the genome of an exogenous eukaryotic virus from a single family? ☐ Yes ☐ No

f. Is the transgenic animal that results from this breeding expected to contain more than one-half of an exogenous viral genome from a single family of viruses? ☐ Yes ☐ No

f. Describe the expected unique characteristics of viable offspring: _____

g. Describe the precautions that will be taken to minimize the possibility that animals could escape confinement: _____

h. Describe the effect on the wild population if an animal were to escape and mate with wild-type:

_____

8. Recombinant or synthetic nucleic acids (rsNA) in animals

☐ *CHECK IF THIS SECTION IS NOT APPLICABLE*

a. Animals as host for recombinant microorganism? ☐ Yes ☐ No

If yes, name of recombinant microorganism: _____

If yes, name of vector: _____

If yes, name of inserted gene: _____

If yes, biological origin of inserted gene: _____

b. Animals as host for rsNA (e.g. modified plasmids)? ☐ Yes ☐ No

If yes, name of vector: _____

If yes, name of inserted gene: _____

If yes, biological origin of inserted gene: _____

c. Animals as host for recombinant eukaryotic cells? ☐ Yes ☐ No

If yes, species of cells: _____

If yes, name of vector: _____

If yes, name of inserted gene: _____

If yes, biological origin of inserted gene: _____

9. Recombinant or synthetic nucleic acids (rsNA) in insects

☐ *CHECK IF THIS SECTION IS NOT APPLICABLE*

a. Construction of transgenic insects? ☐ Yes ☐ No

If yes, Insect species: _____

If yes, Transgene: _____

If yes, biological origin of transgene: _____

If yes, Vector: _____

b. Insects as host for rsNA-modified microorganisms? ☐ Yes ☐ No

If yes, Insect species: _____

If yes, Recombinant microorganism: _____

If yes, Gene(s) encoded by inserted DNA: _____

If yes, biological origin of inserted DNA: _____

If yes, Vector: _____

10. Recombinant or synthetic nucleic acids (rsNA) in plants

☐ *CHECK IF THIS SECTION IS NOT APPLICABLE*

a. Construction of transgenic plants? ☐ Yes ☐ No
   If yes, Plant species: _____
   If yes, Transgene: _____
   If yes, Biological origin of transgene: _____
   If yes, Vector: _____
b. Plants as host for rsNA-modified microorganisms? ☐ Yes ☐ No
   If yes, Plant species: _____
   If yes, Recombinant microorganism: _____
   If yes, Gene(s) encoded by inserted DNA: _____
   If yes, Biological origin of inserted DNA: _____
c. Where will infected plants be located? ☐ Greenhouse ☐ Field ☐ Other:_____
d. Describe procedures for containment of infected plants: _____
   _____
e. Describe how infected plant materials rendered non-infectious: _____
   _____

11. Gene editing technologies (e.g., CRISPR/Cas9, TALEN, Zinc Finger Nucleases, Meganucleases, or any other gene editing technology)

☐ *CHECK IF THIS SECTION IS NOT APPLICABLE*

a. Please list the technology used: _____
b. If CRISPR is involved, are the guide RNA sequence and the Cas endonuclease on the same plasmid or delivery vehicle? ☐ Yes (explain in Overview) ☐ No
   If yes, can the plasmid, vector or delivery vehicle infect a human cell? ☐ Yes ☐ No
c. Does the project involve a viral vector? ☐ Yes (explain in Overview) ☐ No
d. Is this a gene drive experiment? ☐ Yes (explain in Overview) ☐ No
e. Will the research involve embryos or germ line cells (outside of standard transgenic animal protocols?) ☐ Yes (explain in Overview) ☐ No
f. Discuss the potential for off-target effects: _____
g. How many genes have been targeted?_____
   ☐ Single?
   ☐ Multiple? How many? _____
   ☐ Library? List #, i.e. hundreds, thousands, more? _____
      # of unique vectors associated with gene editing library: _____
      # of gene editing sequences targeting each gene in the library (per vector): _____

12. Toxins

☐ *CHECK IF THIS SECTION IS NOT APPLICABLE*

a. Name of Toxin: _____
b. Subtype(s): _____
c. Active toxin? ☐ Yes ☐ No
d. Name of organism that produces the toxin: _____
e. LD50 in humans or rodents: _____
f. Form (e.g., solid/liquid): _____
g. Maximum quantity in possession at any one time: _____
h. If toxin is a Select Agent, is max quantity below allowable limit? ☐ Yes ☐ No
i. How is toxin inactivated: ☐ heat ☐ chemical ☐ radiation ☐ other: _____

13. Infectious agents

☐ *CHECK IF THIS SECTION IS NOT APPLICABLE*

a. Name of organism: _____
b. Strain, subtype, serotype: _____
c. Is antibiotic resistance expressed? ☐ Yes ☐ No
d. Name of antibiotics to which strain is resistant: _____
e. Name of antibiotics to which strain is sensitive: _____
f. Is toxin produced? ☐ Yes ☐ No
   If yes, Name of toxin(s): _____
   If yes, is work conducted with the toxin? ☐ Yes ☐ No
g. Largest volume of organism cultured: _____
h. Is organism concentrated? ☐ Yes ☐ No
i. How is the organism inactivated? ☐ heat ☐ chemical ☐ radiation ☐ other:_____

14. Human blood, cell culture, or unfixed tissue

☐ *CHECK IF THIS SECTION IS NOT APPLICABLE*

a. Samples manipulated: ☐ blood ☐ serum ☐ unfixed tissue ☐ cell culture ☐ other: _____
b. Are procedures done in a biological safety cabinet? ☐ Yes ☐ No
c. Are sharps (e.g., needles, scalpels, Pasteur pipets) used? ☐ Yes ☐ No
   Are sharps disposed into sharps containers? ☐ Yes ☐ No
d. Have all personnel completed bloodborne pathogens training? ☐ Yes ☐ No
e. If human subjects are involved, has this work been registered with the Institutional Review Board?
   ☐ Yes ☐ No

15. Non-human primate (NHP) blood, or unfixed tissue

☐ *CHECK IF THIS SECTION IS NOT APPLICABLE*

a. Samples manipulated: ☐ blood ☐ serum ☐ unfixed tissue ☐ cell culture ☐ other: _____
b. Are procedures done in a biological safety cabinet? ☐ Yes ☐ No
c. Are sharps (e.g., needles, scalpels, Pasteur pipettes) used? ☐ Yes ☐ No
   Are sharps disposed into sharps containers? ☐ Yes ☐ No
d. Have all personnel who work with NHP material been educated on the risks of *Cercopithecine herpesvirus I* (monkey B virus)? ☐ Yes ☐ No

Please complete Section III on the next page, regardless of your selections in Section II.

SECTION III

1. Containment equipment available:

Biological safety cabinet: ☐ Yes ☐ No
Date of last BSC certification: _____
Containment centrifuge: ☐ Yes ☐ No
Other: _____
Shared/Core Facility: _____

2. If live vertebrate animals are involved:

Animal species: _____
Animal housing location: _____

3. Overview. Please briefly describe the experimental design and purpose/objectives of your research, highlighting the methodology used and/or the use of infectious microorganisms if applicable. Please write in layman's terms. *Do not cut and paste from a grant application.*

4. Risk Assessment and Control. Please provide a brief protocol-specific risk assessment. Include consideration of agent pathogenicity, virulence, infectious dose, route of transmission, host range, and stability, as well as the likelihood of exposure and consequences of exposure. How will identified risks be controlled (e.g., PPE, work practices, etc.)?

5. Training. Please describe training that will be provided to lab staff. This should include potential for zoonoses or lab acquired infections, considerations for immunocompromising conditions, proper operation of lab equipment, general safety information, reporting requirements, etc. Is there a process for working under supervision until competency is achieved? How is training documented?

6. Post-exposure procedures. Please describe procedures that will be followed in the event of an accidental release or exposure, including first aid and reporting requirements. **Note:** Spills or accidents resulting in release or potential exposure to rsNA must be reported to the BSO in compliance with the requirements of the NIH Guidelines.

7. Proposed Containment:

- ☐ BSL1
- ☐ ABSL1
- ☐ BSL2
- ☐ ABSL2
- ☐ BSL1-Plant
- ☐ BSL2-Plant

7. Please select all applicable section(s) of the *NIH Guidelines*:

Sections III-A,B,C: Experiments requiring NIH and IBC approval PRIOR to initiation:	
☐	III-A: Deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally if such acquisition could compromise the use of the drug to control disease.
☐	III-B: Cloning of toxin molecules with LD_{50} of less than 100 ng / kilogram body weight.
☐	III-C: Transfer of rsNA to human research participants.
Section III-D - Experiments that require IBC approval PRIOR to initiation:	
☐	III-D-1: Experiments using Risk Group 2, 3, or 4 agents as host-vector systems.
☐	III-D-2: Experiments in which DNA from Risk Group 2, 3, or 4 agents is cloned into nonpathogenic prokaryotic or lower eukaryotic host-vector systems.
☐	III-D-3: Experiments involving the use of recombinant or reassortant viruses in tissue culture systems; or defective recombinant viruses in the presence of helper virus or packaging cells in tissue culture systems (this includes all eukaryotic viruses).
☐	III-D-4-a: Experiments that generate transgenic animals, including insects (with the exception of transgenic rodents requiring BL1 containment. See III-E-3 and III-F).
☐	III-D-4-b: Experiments involving viable rsNA-modified microorganisms tested on whole animals.
☐	III-D-5: Experiments involving whole plants that require BL3 or BL4 containment.
☐	III-D-6: Experiments involving more than 10 liters of culture.
☐	III-D-7: Experiments involving human influenza strains H2N2, 1918 H1N1, and/or highly pathogenic H5N1.
Section III-E - Experiments that require registration simultaneous with initiation:	
☐	III-E-1: Introduction into cultured cells of any rsNA containing greater than half but less than 2/3 of a eukaryotic viral genome (with the exception of Risk Group 3 or 4 agents).
☐	III-E-2: Experiments involving whole plants that require BL1 or BL2 containment.
☐	III-E-3: Generation of rodents in which the animal's genome has been altered by rsNA, requiring BL1 containment.
☐	III-E: Experiments not specified on this sheet.
Section III-F - Experiments that are exempt but still require registration:	
☐	III-F-1: Experiments that use synthetic nucleic acids that can neither replicate nor generate nucleic acids capable of replicating in any living cell; are not designed to integrate into DNA, and do not produce a toxin that is lethal for vertebrates at an LD50 of <100 ng/kg body weight.
☐	III-F-8: Cloning of all other DNA in *E. coli* K12, *S. cerevisiae*, and *B. subtilis* host-vector systems (with the exception of DNA from Risk Group 3 or 4 pathogens).
☐	III-F-8: Introduction into cultured cells of any rsNA containing less than half of a eukaryotic viral genome (with the exception of Risk Group 3 or 4 pathogens).
☐	III-F-8: Purchase or transfer of transgenic rodents that require BL1. (Appendix C-VII)
☐	III-F-8: Breeding experiments to generate transgenic rodents that may be housed under BL1, with the exception of those listed in Section III-E. (Appendix C-VIII)

Principal Investigator: *"By submitting this registration, I accept responsibility for the safe conduct of work with this material at the established biosafety level. I will ensure that all personnel receive training in regard to proper safety practices and personal protective equipment needed for this work."*