



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 pertain 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? 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 vertebrate animal

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)

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 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 No
- d. Is this a gene drive experiment? Yes No
- e. Will the research involve embryos or germ line cells (outside of standard transgenic animal protocols?) Yes 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

- h. Name of organism: _____
- i. Strain, subtype, serotype: _____
- j. Is antibiotic resistance expressed? Yes No
- k. Name of antibiotics to which strain is resistant: _____
- l. Name of antibiotics to which strain is sensitive: _____
- m. Is toxin produced? Yes No
 If yes, Name of toxin(s): _____
 If yes, is work conducted with the toxin? Yes No
- n. Largest volume of organism cultured: _____
- o. Is organism concentrated? Yes No
- p. 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. Do any lab procedures create aerosols? Yes No
 List procedures that create aerosols: _____
 Are these procedures done in a biological safety cabinet? Yes No N/A
- c. Are sharps (e.g., needles, scalpels, Pasteur pipets) used? Yes No
 Are sharps disposed into sharps containers? Yes No
- d. Have all personnel who work with human material completed bloodborne pathogens training?
 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. Do any lab procedures create aerosols? Yes No
 List procedures that create aerosols: _____
 Are these procedures done in a biological safety cabinet? Yes No N/A
- 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 1* (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: _____

2. If vertebrate animals are involved:

Animal species: _____

Animal housing location: _____

IACUC protocol number(s): _____

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 that require 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 LD₅₀ 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 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 by embryo injection of transgenic rodents requiring BL1 containment.

[III-E-3-a](#): Breeding experiments to generate transgenic rodents that contain more than 50% of the genome of an exogenous eukaryotic virus, or in which the transgene is under the control of a gammaretroviral LTR.

[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](#): Breeding experiments to generate transgenic rodents that may be housed under BSL1, with the exception of those listed in Section III-E.

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.”*