IBC MAIN APPLICATION FORM

Previous IRBNet Number (If a renewal application):	Click here to enter text.

1: PRINCIPAL INVESTIGATOR INFORMATION

1.1. PRINCIPAL INVESTIGATOR INFORMATION

Principal Investigator: Click here to enter text.
Position/Title: Click here to enter text.
Department/College: Click here to enter text.
Office/Cell Phone #:
Email Address: Email address
Protocol Title: (for this proposal) Click here to enter text.
Will this project be funded by a grant, contract, or any pending grants or contracts? ☐ Yes ☐ No
Grant Title: (if different from IBC protocol) Click here to enter text.
Funding Source: (provide funding source/grant #): Click here to enter text.

1.2. BIOLOGICAL MATERIALS CHECKLIST

1.2.1. Check all that apply to proposed work:

- ☐ Sharps
- ☐ Human blood, tissue, or bodily fluid.
- ☐ Transgenic and/or pathogenic plants.
- ☐ Recombinant or synthetic nucleic acid molecules.
- ☐ Infected or potentially infected cell lines.
- ☐ Animal blood, tissue, or bodily fluid.
- ☐ Radioactive materials.
- ☐ Shipping of biological materials.
- ☐ Aerosol generating procedures
- ☐ Biohazardous agents and/or toxins.
- ☐ Gene therapy/vaccine experiment/human subjects.
- ☐ Transgenic animals (including invertebrates).
- ☐ Cell lines or primary cell lines.
- ☐ Microorganisms.
- ☐ Import/Export to/from US.
- ☐ Gene drives or the possibility to generate a gene drive.

1.3. Biosafety Level

1.3.1. Indicate the biosafety level of the proposed work.
NOTE: If applicable, please attach the BSL-2 door signage to your IRBNet package (sign template). Use the drop-down menu in the template to select the biosafety level.

☐ BSL 1 ☐ BSL 2 ☐ BSL 1 & BSL 2

1.4. Subject Population Checklist

1.4.1. Will this project involve human, animal or plant pathogens, or biological toxins?

☐ Human Subjects
☐ Animals
☐ Not Applicable
☐ Other

If 'OTHER' please describe:
Click here to enter text.

1.4.2. Please list the infections agents or biological toxins to be used and indicate appropriate categories:

Table 1.4.A.

To add additional agents, click on the + at the end of each box.

NAME OF INFECTIOUS AGENT OR BIOLOGICAL TOXIN	HUMAN HAZARD? (YES/NO)	ANIMAL HAZARD? (YES/NO)	INSECT HAZARD? (YES/NO)	LOCATION OF ORIGIN
Click here to enter text.	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	Click here to enter text.
Click here to enter text.	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	Click here to enter text.
Click here to enter text.	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	Click here to enter text.
Click here to enter text.	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	Click here to enter text.
Click here to enter text.	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	Click here to enter text.

1.4.3. If this project will involve infectious agents or biological toxins that affect humans, please describe symptoms, severity of disease, vulnerable populations and mode of transmission (fecal-oral, direct contact, aerosol, etc.)
Click here to enter text.

1.5. Research Location(s)

Please list the research activities, building, room number, and the biosafety level for that space and research activity.

Table 1.5.A. Research Activities

To add additional research activities, click on the + at the end of each box.

RESEARCH ACTIVITIES	BUILDING	ROOM	BIOSAFETY LEVEL	SHARED ROOM? (YES/NO)
Click here to enter text.	Click here to enter text.	Click here to enter text.	☐ BSL 1 ☐ BSL 2	☐Yes ☐ No
Click here to enter text.	Click here to enter text.	Click here to enter text.	☐ BSL 1 ☐ BSL 2	☐Yes ☐ No
Click here to enter text.	Click here to enter text.	Click here to enter text.	☐ BSL 1 ☐ BSL 2	☐Yes ☐ No
Click here to enter text.	Click here to enter text.	Click here to enter text.	☐ BSL 1 ☐ BSL 2	☐Yes ☐ No
Click here to enter text.	Click here to enter text.	Click here to enter text.	☐ BSL 1 ☐ BSL 2	☐Yes ☐ No

1.6. Biological Materials Storage

List locations of biological safety equipment (biosafety cabinet, autoclave). Include most recent certification date for biosafety cabinets.

Table1.6.A. Biological Materials Storage

To add additional locations, click on the + at the end of the box.

BUILDING	ROOM	FREEZER	REFRIGERATOR	INCUBATOR	OTHER
Click here to enter text.	Click here to enter text.	☐Yes ☐ No	☐Yes ☐ No	☐Yes ☐ No	Click here to enter text.
Click here to enter text.	Click here to enter text.	☐Yes ☐ No	☐Yes ☐ No	☐Yes ☐ No	Click here to enter text.

Click here to enter text.	Click here to enter text.	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	Click here to enter text.

Table 1.6.B. Biological Safety Cabinets

BIOLOGICAL SAFETY EQUIPMENT USED	BUILDING ROOM	MOST RECENT CERTIFICATION DATE	SERIAL NUMBER
Click here to enter text.	Click here to enter text.	Click here to enter a date.	
Click here to enter text.	Click here to enter text.	Click here to enter a date.	
Click here to enter text.	Click here to enter text.	Click here to enter a date.	

1.7. IMPORTING & EXPORTING

1.7.1. Will you be exporting/importing samples (tissues, blood, organ, etc.), plasmids, or research products outside of the United States of America?

☐ Yes ☐ No

1.8. IRB/IACUC REVIEW

1.8.1. Has this project been approved or is being reviewed by the IACUC or IRB?

☐ YES, there is an associated IRB protocol. List protocol number. If approved, attach DU IRB approval letter.

☐ YES, there is an associated IACUC protocol. List protocol number. If approved, attach DU IACUC approval letter.

☐ NO, this research does not require IACUC or IRB review/approval.

2: NIH REVIEW CATEGORY & SUBCATEGORY

Check all the categories, subcategories and information that apply.
NIH Office of Science Policy Website: https://osp.od.nih.gov/

Does your project include the use of recombinant or synthetic nucleic acid molecules?

☐ Yes, complete the table below ☐ No, skip to section 3

CATEGORY	OVERSIGHT BY	INCLUDES/SUBCATEGORIES
☐ III-A	NIH Director, RAC & IBC	Studies that involve the deliberate transfer of drug resistance to microorganisms (not know to acquire the trait naturally) that can compromise the use of the drug to control the microorganism and its disease in humans, veterinary medicine or agriculture
☐ III-B	NIH/OBA & IBC	This category is limited to cloning of genes that encode for toxin molecules with LD-50<100 nanograms/kg body weight (e.g., botulinum, tetanus, diphtheria toxins).
☐ III-C	RAC, IRB & IBC	Transfer of recombinant or synthetic DNA, or DNA or RNA derived from recombinant DNA, into one or more human subjects.
☐ III-D	IBC Approval before initiation	☐ D-1: Experiments using Risk Group 2. Risk Group 3, Risk Group 4 or restricted agents as host-vector systems. ☐ D-2: Experiments in which nucleic acids from Risk Group 2, Risk Group 3, Risk Group 4 or restricted agents is cloned into non-pathogenic prokaryotic or lower eukaryotic host-vector systems. For cloning toxin molecules with LD50 of less than 100 nanograms per kilogram body weight check section III-B above. Section D-2 does not apply. ☐ D-3: Experiments involving the use of infectious DNA or RNA viruses or defective DNA or RNA viruses in the presence of a helper virus in tissue culture systems. Experiment is likely to enhance pathogenicity. ☐ Yes ☐ No Experiment extends the host range. ☐ Yes ☐ No ☐ D-4: Experiments involving whole animals in which the animal's genome has been altered by stable introduction of r/sNA, or r/sNA derived there from, into the germ-line (transgenic animals) and experiments involving viable r r/sNA-modified microorganisms tested on whole animals. For the latter, other

CATEGORY	OVERSIGHT BY	INCLUDES/SUBCATEGORIES
		than viruses which are only vertically transmitted, the experiments may not be conducted at BL1-N containment. A minimum containment of BL2 or BL2-N is required (see E-3 for BSL-1 transgenic rodent experiments). Fraction of viral genome being utilized may lead to productive infection. ☐ Yes ☐ No Recombinant r/sNA: source is greater than 2/3 eukaryotic viral genome. ☐ Yes ☐ No ☐ D-5: Experiments involving the generation of transgenic plants or use of recombinant microorganisms or recombinant insects in plants. (For cloning of toxin molecules with LD50 of less than 100 nanograms per kilogram body weight, see section III-B above. Section D-5 does not apply.) ☐ D-6: Experiments involving cultures of 10L increments or greater.
☐ III-E	IBC notified simultaneous with initiation	☐ E-1: Experiments involving less than 2/3 of a eukaryotic virus genome. All viruses from a single family being considered identical. Do cells contain helper viruses for family of viruses being used? (If yes, see III-D3). ☐ Yes ☐ No ☐ E-2: Experiments involving the generation of transgenic plants or use of recombinant microorganisms or recombinant insects in plants. For those not described in III-A, III-B, III-C, III-D or III-F. ☐ E-3: Experiments involving the generation of transgenic rodents for BSL-1 only (see III-D4 for experiments requiring BSL-2, 3 or 4).
☐ III-F	Exempt Experiments. DU policy requires Biosafety Approval	☐ 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), and 2.) are not designed to integrate into DNA, and (3) do not produce a toxin that is lethal for vertebrates at an LD50 of less than 100 nanograms per kilogram body weight. If a synthetic nucleic acid is deliberately transferred into one or

CATEGORY	OVERSIGHT BY	INCLUDES/SUBCATEGORIES
	Form Submittal	more human research participants and meets the criteria of Section III-C, it is not exempt under this Section. ☐ 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. ☐ F-3: Those that consist solely of the exact recombinant or synthetic nucleic acid sequence from a single source that exists contemporaneously in nature. ☐ F-4: Those that consist entirely of nucleic acids from a prokaryotic host, including its indigenous plasmids or viruses when propagated only in that host (or a closely related strain of the same species), or when transferred to another host by well-established physiological means. ☐ F-5: Those that consist entirely of nucleic acids from a eukaryotic host including its chloroplasts, mitochondria, or plasmids (but excluding viruses) when propagated only in that host (or a closely related strain of the same species). ☐ F-6: Those that consist entirely of DNA segments from different species that exchange DNA by known physiological processes, though one or more of the segments may be a synthetic equivalent. ☐ 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. ☐ F-8: Those that do not present a significant risk to health or the environment (see Section IV-C-1-b-(1)-(c))

3: SPECIFIC AIMS OF PROJECT AND PROTOCOLS USED

3.1. SPECIFIC AIMS

3.1.1. Provide an overall summary of the project and briefly explain in **language understandable to the general public** the specific aim(s) of the study.
Click here to enter text.

3.2. BENEFITS

3.2.1. Explain in **language understandable to the general public** how the information gained in this study will benefit human or animal health, the advancement of knowledge, and/or server the good of society.
Click here to enter text.

3.3. OUTLINE OF PROTOCOLS

3.3.1. Outline the biohazard control plan for recombinant DNA work and other biohazardous work.

- Briefly describe the general types of experimental procedures that will be performed.
- Address the potential sources of risk to personnel (aerosol generation, needle sticks, etc.) and/or the environment, and how these risks will be managed.
- Describe safety devices that will be used (e.g. biosafety cabinets, hand washing facilities, puncture resistant sharps containers, etc.)
- Include decontamination/disinfection processes.
- Include plans for disposing of materials.

Click here to enter text.

4: BIOLOGICAL MATERIALS IN PROJECT

4.1. List the recombinant DNA used in the proposed work.

- ✓ Include cloned gene(s), vectors used; give both name and type of each vector.
- ✓ If using Lentiviral vectors, complete Appendix A: Lentivirus Assessment (LVRA).

Click here to enter text.

4.2. List the genes described above that will be expressed:
Click here to enter text.

4.3. List organism(s) or cell lines are used in the proposed work:
Click here to enter text.

4.4. If animal models are used (including vertebrates or invertebrates), please complete the following:

- Type of animal:
  ☐ Vertebrate

☐ Invertebrate

- Are any animals genetically modified (transgenic, gene edited, or recombinant), including purchased or lab generated?
  ☐ Yes ☐ No

If YES, briefly describe:

- Nature of modification
- Whether modification affects pathogenicity, transmissibility, or environmental persistence
- Containment level (ABSL if applicable)
- Do manipulated animals pose additional hazards (e.g., shedding biological material, increased virulence)?
  ☐ Yes ☐ No

If YES, describe containment and mitigation measures.
Click here to enter text.

4.5. List any materials of human or mammalian origin (blood, tissues, fluids, etc.)

- ✓ Indicate whether each material is certified pathogen free.
- ✓ Attach documentation that certifies cell lines are pathogen free.
- ✓ Provide IRB documentation (i.e., IRB approval, protocol number) in 1.9 if obtaining specimens from research subjects.

Click here to enter text.

If applicable, explain what the specific product of the gene expressed will be (i.e., tissue culture or animals) and if there is any anticipated toxicity.
Click here to enter text.

5: PERSONNEL AND TRAINING

5.1. Please list the PI and other personnel who will be handling biological agents. Include personnel who are graduate level or higher or who will have a role in training other lab members.

TABLE 5.1.A. PERSONNEL AND TRAINING

To add additional people, click on the + at the end of each box.

NAME	PHONE #	EMAIL ADDRESS	CREDENTIALS	COMPLETED TRAINING	ROLE IN PROJECT
Click here to enter text.		Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.		Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.		Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.		Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.		Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.

5.2. Briefly describe the training plan for lab members who lack experience in handling biological materials below. Include who will lead the training as well as the practices and techniques that will be taught.
Click here to enter text.

6. PROCEDURES FOR LABORATORY SAFETY AND EXPERIMENTAL PROCEDURES

6.1. LABORATORY PPE

I understand University policy requires that PPE must be worn when working with laboratory hazards (chemical, biological, and radioactive materials).

At the minimum, this must include:

- Laboratory coats (or other protective clothing such as aprons, scrubs, coveralls, etc.)
- Safety goggles or glasses
- Gloves resistant to the material used
- Appropriate footwear (closed at the hell and toe)

Sandals must not be worn with working in the laboratory. Other protective equipment, such as splash goggles, face shields, aprons, thermal or cut-resistant gloves, hearing protection or respirators, must be worn when conditions dictate.

In a class situation, student shall purchase or obtain the necessary and approved PPE designated by the department or instructor responsible for the course. Students must be trained in the proper usage and care of the PPE.

6.2. Special Precautions

Please list any special precautions, in addition to the PPE and the regulatory guideline requirements, which may be employed in the laboratory for safety and waste handling. If this question is not applicable, please indicate N/A.
Click here to enter text.

7: SENDING OR RECEIVING BIOLOGICAL SAMPLES

This includes genetically modified organisms, body fluids, tissue samples, blood samples, and pathogens.

If you will be sending or receiving biological samples, please contact the IP/Tech Transfer Office at: 1-4230 or techtransfer@du.edu.

Will you be:

- ☐ RECEIVING samples from outside of DU? Choose an item.
- ☐ SENDING samples outside of DU? Choose an item.

IF YES is selected for either, please provide the following information:

7.1.

What outside organization(s) will be sending or receiving samples?
Click here to enter text.

7.2.

What are the samples that will be sent or received?
Click here to enter text.

8: PRINCIPAL INVESTIGATOR AGREEMENT

A checked box indicates agreement by the PI for the statement checked.

☐ **IBC EDUCATION:** I confirm that all individuals working on this protocol have completed the required CITI Complete Biosafety Training and maintain valid (within 4 years) certification.

☐ **EH&S EDUCATION**: I confirm that all individuals working on this protocol have completed the required DU Environmental Health and Safety Laboratory Safety Training.

☐ **Occupational Health and Safety:** I confirm that all individuals listed on this protocol as working with biological hazards have completed the **Occupational Health Review Form** or will be required to do so before being permitted to begin work in the lab.

☐ **CONTAINMENT BREACH**: I will immediately report any biological hazard spills to the DU Chemical & Hazardous Materials Manager in EHS and document spills in my Annual Report to the IBC.

☐ **AMENDMENTS:** I will submit an amended application and receive IBC approval prior to instituting any changes in the biological materials used in the project as described in the approved application or adding new research personnel.

☐ **TRAINING:** I will keep written and organized documentation of training sessions in my lab, and make this documentation available to the IBC during periodic inspections and/or audits. For BSL2 and above, I (or a designated lab member) will train project personnel involved in work using biological hazards above BSL1.

☐ **CONTINUING REVIEW:** I will complete an annual Post Approval Monitoring (PAM) meeting with the IBC Administrator each year during the first, second, third and fourth year anniversary month of the date of approval.

☐ **FINAL REPORT:** I will notify the IBC when the study is complete either by completing a Final Report Form when the work is complete or at the five-year anniversary from the date of approval, whichever comes first.

☐ I authorize individuals listed on this application to conduct procedures involving biological materials and I accept responsibility for their oversight in the conduct of this proposal.