FOR OFFICE USE ONLY: IBC PROTOCOL # _____ STATUS: _____
ANIMAL WORK: _____ CONTAINMENT BSL: _____ RECOMBINANT DNA: _____
TRAINING COMPLETE: _____

University of North Dakota
Institutional Biosafety Committee (IBC)
Research Registration Document
Please send your completed document to the Institutional Review Board (IRB) Office

INSTRUCTIONS

Be sure to save the application PDF to your computer before you begin completing the form. You may not be able to save your changes if you edit this form in a web browser. Mac users please use Adobe Acrobat Reader or Adobe Acrobat Pro to fill out the registration document.

All Principal Investigators conducting biological research must register with the University of North Dakota (UND) Institutional Biosafety Committee (IBC) to ensure that their research complies with UND biosafety regulations and National Institutes of Health (NIH) recombinant DNA guidelines. Consequently, it is critical that the IBC receive sufficiently detailed information to fulfill its review and approval mandate. This IBC Registration Document (RD) is the critical instrument for the IBC to accomplish that review and approval responsibility. **If you are performing rDNA or infectious/tumorigenic material activities or biological research that are not detailed in an approved RD, you may be in violation of federal regulations and/or university policies.**

This form must be completed and submitted to UND's Institutional Review Board Office for approval prior to the initiation of research involving recombinant DNA and/or infectious agents, as described in the NIH and Centers for Disease Control and Prevention (CDC) guidelines. Attach additional sheets if needed, to fully answer any section.

FAILURE TO PROVIDE ALL INFORMATION REQUESTED WILL LEAD TO A DELAY IN PROCESSING YOUR REQUEST!

Registration Documents are approved for a period of 3 years. Continued activity past 3 years will require a new Registration Document to be submitted. However, the annual review form needs to be submitted every year. Submitting a Modification is Not a Renewal of an existing Registration Document.

Multiple Agent Approval in One Registration Document: The inclusion of multiple agents in a single Registration Document may hinder the IBC's ability to adequately review proposed activities. In general, if your request includes more than one genus or type of agent, that would affect the risk profile, please consider submitting additional registration documents to the IBC for those differing agents instead of an all-inclusive request. If the IBC concludes that the activities are indeed too different, and that the information requested is not sufficiently detailed for review purposes, the committee may request additional RD's to cover activities deemed too divergent to be described together. This would result in a delay for approval of those activities.

If you need help or have questions about how to complete this application, please contact the IBC Chair, Matthew Nilles, at matthew.nilles@UND.edu, or the Biological Safety Officer, Heather Vinson, at heather.vinson@UND.edu.

Please email a **signed copy** of the application to:
UND.ibc@UND.edu.

PLEASE CONTINUE TO THE NEXT PAGE TO BEGIN COMPLETING THE FORM

☐ **NEW SUBMISSION** ☐ **RENEWAL – PREVIOUS IBC# _____**

I. ADMINISTRATIVE INFORMATION:

Principal Investigator:			
Department:		**Phone No:**	
Building, Office Room No., Mail Code		**Email:**	
Co-Investigator:			
Department:		**Phone No:**	
Building, Office Room No., Mail Code		**Email:**	
PROJECT TITLE:			
Funding Agency:		**UND Proposal or Award #:**	
Dates of Project:	**From:**	**To:**	

The University's IBC is comprised of both active researchers and nonscientists. Regardless of backgrounds, each member has one vote, and it is therefore particularly important that the language of the application be understood by all. This applies to all sections of the application, but it is especially important that the goals and justifications of the proposed research be spelled out in the clearest possible terms.

NOTE: Upon approval, this disclosure may become a public record, so please do not disclose proprietary information.

II. NON-TECHNICAL SYNOPSIS: Provide a synopsis in layman's terms of proposed research project as well as information on the experiments you will be performing.

III. IDENTIFICATION OF POTENTIAL BIOHAZARDS - Check all that apply

- ☐ Recombinant or Synthetic Nucleic Acid Molecules
- ☐ Viruses and Virus Vectors
- ☐ Infectious Agents (Bacteria, Eukaryotic Pathogens, Protozoa or Viruses pathogenic to plants and animals)
- ☐ Hazardous Chemical or Biological Toxins
- ☐ Human Blood/Tissue/Cell Lines (Bloodborne Pathogens Training Required) (https://und.edu/research/resources/institutional-biosafety-committee.cfm)
- ☐ Arthropods
- ☐ Vertebrate Animal Usage
- ☐ Plant Studies
- ☐ Nanomaterials
- ☐ Radioisotopes (Must be registered with the Radiation Safety & Hazardous Materials Committee)

NOTE: ***If you did not check ☒ any of the boxes in this section, you are not required to submit an IBC protocol.***

IV. RISK ASSESSMENT

Have you performed a risk assessment for the proposed activity?

☐ Yes ☐ No

NOTE: ***A scientist (PI), trained and knowledgeable in appropriate laboratory techniques, safety procedures, and hazards associated with handling infectious agents or materials must be responsible for the conduct of work with any infectious agents or materials. This individual should consult with the IBC Chair or the Biological Safety Officer with regard to risk assessment if assistance is needed.*** (**NOTE:** A template that can be utilized for risk assessment is available on the Office of Safety website (http://und.edu/public-safety/public-safety/biological.cfm)

V. LAB SPECIFIC SAFETY MANUAL

Is a lab specific manual that identifies the hazards that will be encountered, and that specifies practices and procedures designed to minimize or eliminate exposures to these hazards maintained by the PI? (**NOTE:** A template of the lab specific manual can be found on the Office of Safety website (http://und.edu/public-safety/public-safety/biological.cfm)

☐ Yes ☐ No

VI. COMPLIANCE CHECKLIST

Does the Project involve the use of:

☐ **Select Agents**

The National Select Agents Registry Program (NSAR) (http://www.selectagents.gov/), a joint program of the CDC and the USDA Animal and Plant Health Inspection Service (APHIS), oversees the activities of possession, use and transfer of biological agents and toxins that have the potential to pose a severe threat to public, animal or plant health, or to animal or plant products. The NSAR currently requires registration of facilities including government agencies, universities, research institutions, and commercial entities that possess, use or transfer biological agents and toxins.

NOTE: If you plan to use or are using any of the viruses, bacteria, fungi, rickettsial agents, or toxins on the select agent list, please contact the UND Biological Safety Officer (701-777-2444) for information.

☐ **Live Vertebrate Animals**

(If yes, a protocol must be submitted and approved by IACUC prior to use of any animals or Approved Protocol Number _____)

☐ **Human Subjects**

(A protocol must be submitted and approved by the UND IRB prior to the involvement of human subjects or Approved Protocol Number _____)

☐ **Export Control** (Does your proposed activity involve information, technology, materials or intellectual property that has been deemed to be sensitive or protected against open publication or disclosure, i.e. classified, proprietary, business sensitive, sponsor restricted, etc. *If yes, you may be subject to Federal Export Controls Regulations. Contact the UND Export Control Officer (701-777-4152) for information on Export Controls.*

VII. PERMIT REQUIREMENTS

1. Are possession permits required for this biohazardous agent?
   ☐ Yes ☐ No (If "Yes" Please include a copy)
2. Provide the source of the biohazardous agent that will be used in this activity:

3. Do you currently possess the biohazardous agent that is intended for use in this Registration Document?
   ☐ Yes ☐ No
4. Are import permits required for this biohazardous agent? (Reference "Guidance on Import Permit Program (IPP) Requirement" see http://www.cdc.gov/od/eaipp/ and/or http://www.aphis.usda.gov/wps/portal/aphis/resources/permits)
   ☐ Yes ☐ No (If "Yes" Please include a copy)

VIII. PROJECT DESCRIPTION:

Provide a succinct narrative of the experimental protocol proposed involving biohazardous material. Provide enough detail for the committee to evaluate the containment level required. Attach a copy of the grant proposal abstract or project summary if desired.

IX. BIOSAFETY LEVEL DETERMINATION

1. Based on your Risk Assessment for the proposed activities, provide the following information using the NIH guidelines for recombinant or synthetic nucleic acid research (https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.html)

a. Applicable section of NIH Guidelines:

	Please check all boxes that apply		**NIH Guidelines Reference**
D.1	☐	Use of animal cells/cell lines or tissues (e.g. tissue culture research)	II-A-3, Appendix C-1
D.2	☐	Use of human cells/cell lines or tissues (e.g. Human blood, 293 cell lines, CSF)	II-A-3
D.3	☐	Transfer of Drug Resistance trait to microorganisms	III-A-1-a
D.4	☐	Use or cloning of toxin molecule genes	III-B-1
D.5	☐	Use of or the cloning of genes from, or into a Risk Group 2, 3, 4 or restricted agent	III-D-1, 2
D.6	☐	Use of virus or viral particles	III-D-3, III-E-1
D.7	☐	Propagating culture volumes exceeding 10 liters	III-D-6
D.8	☐	Creation or Use of c-DNA/genomic libraries	III-E, III-F
D.9	☐	Cloning and vector construction in bacteria and yeasts	III-E, III-F
D.10	☐	Use of rDNA molecules for detection purposes (e.g. probes)	III-F
D.11	☐	Expression of rDNA products in cultured cells	III-E, III-F
D.12	☐	Administration of rDNA product into humans (e.g. Gene Transfer Protocol)	III-C-1
D.13	☐	Administration of rDNA material into animals (e.g. transformed cells, vectors)	III-D-4
D.14	☐	Experiments involving transgenic rodents	III-E-3
D.15	☐	Experiments involving whole transgenic plants	III-D-5
D.16	☐	This is an EXEMPT project, per Section II.B.	III-F
D.17	☐	Select Agent or Toxins	

b. Risk Group (Agent Specific): ☐ RG1 ☐ RG2 ☐ RG3 ☐ RG4

c. Applicable Physical Containment/Biosafety Level (Facility specific): *Check all that apply*

Standard Laboratory Experiments: ☐ BL1 ☐ BL2 ☐ BL3 ☐ BL4

POLICY: All cell and organ cultures of human origin, including well established cell lines, shall be handled in accordance with the OSHA Bloodborne Pathogens Standard and under Biosafety Level 2 (BSL-2) containment.

Recombinant or Synthetic Nucleic Acid Involving Plants: ☐ BL1-P ☐ BL2-P ☐ BL3-P ☐ BL4-P

Recombinant or Synthetic Nucleic Acid Involving Animals: ☐ BL1-N ☐ BL2-N ☐ BL3-N ☐ BL4-N

X. RECOMBINANT OR SYNTHETIC NUCLEIC ACID MOLECULES

1. My proposed activity involves the use or creation of recombinant or synthetic nucleic acid molecules?
   ☐ Yes ☐ No **(If "No", you may skip to section XI)**
2. From what organism is the cloned nucleic acid derived? Please give scientific name and common name of the organism.

3. If the cloned nucleic acid is from a pathogen, what is the Risk Group? _____
4. What is the source(s) of the inserted nucleic acid sequence (e.g. library, PCR, synthetic oligo, etc.)

5. Describe all hosts to be used for the cloned nucleic acid and the 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.

6. Will a gene product be expressed from the cloned nucleic acid?
   ☐ Yes ☐ No
7. Are you proposing to grow cultures of recombinant or synthetic nucleic acid of more than 10 liters in a single experiment?
   ☐ Yes ☐ No
8. Transgenic animals or plants:
   a. Will your activity involve the use of transgenic animals or plants?
   ☐ Yes ☐ No
   If "yes" provide information on: strains, genetic traits, and the intended use.

   b. Please indicate how these animals will be procured. This information is intended to inform the committee if animals will be purchased from a vendor, transferred from another institution, or produced here at UND.

9. Describe handling, decontamination and or disposal of potentially contaminated waste:

XI. VIRUSES AND VIRUS VECTORS

1. My proposed activity involves the use of viruses or viral vectors?
   ☐ Yes ☐ No **(If "No", you may skip to section XIII)**
2. My proposed activity involves the use of Lentiviruses and Lentiviral vectors (e.g. FIV, HIV, SIV, etc.)?
   ☐ Yes ☐ No (If "Yes", go to section XII)
3. List viruses and/or viral vectors used:
   a. Specify the virus family and/or subfamily (e.g. herpesvirus, oncogenic retrovirus, adenovirus, adeno-associated virus, etc.).
   b. State the species of origin for each virus or vector used.
4. Is the virus/viral vector able to enter or infect human cells?
   ☐ Yes ☐ No (If "Yes", indicate whether it is a productive or limited infection, and state whether infection can cause disease).

5. Is a helper virus used in this project?
   ☐ Yes ☐ No (If "Yes", describe the helper virus used)

6. Is the virus/viral vector replication defective?
   ☐ Yes ☐ No (If "Yes", describe the deletions rendering it defective)

7. Has the preparation of replication-defective vectors been tested for the presence of replication competent virus?
   ☐ Yes ☐ No
   (If "Yes", provide details of the assay used)
   (If "No", what is the likelihood of conversion to replication-competent virus?)

XII. LENTIVIRAL VECTORS

1. List the specific virus or strain and species of origin (e.g. HIV, human; FIV, feline)

2. Is the lentivirus/lentiviral vector obtained from a commercial source?
   ☐ Yes ☐ No
   (If "Yes", provide the name of the commercial source)
   (If "No", provide the source of lentivirus/lentiviral vector (e.g. the name of the institution or individual supplying the material)

3. Is the lentivirus/lentiviral vector generated from a multi-component system? (e.g. separate plasmids for packaging, envelope and gene transfer)
   ☐ Yes ☐ No (If "Yes", describe the system used)

4. Is the lentivirus/lentiviral vector pseudotyped (e.g. expressing a different envelope gene)?
   ☐ Yes ☐ No (If "Yes", provide whether the pseudotyping alters the host and cell tropism)

5. Is the lentivirus/lentiviral vector replication-defective?
   ☐ Yes ☐ No (If "Yes", describe the deletions rendering it defective)

6. Has the preparation of replication-defective vector been tested for the presence of replication-competent virus?
   ☐ Yes ☐ No
   (If "Yes", provide details of the assay used)
   (If "No", what is the likelihood of conversion to replication-competent virus?)

XIII. INFECTIOUS AGENTS (ALSO APPLICABLE FOR SECTION XI AND XII)

1. My research activity involves the use of infectious agents?
   ☐ Yes ☐ No **(If "No", you may skip to Section XIV)**
2. Guidelines Section and Biosafety Level: Based on your Risk Assessment for the infectious agent, provide the following information using the BMBL 5th Edition at: http://www.cdc.gov/biosafety/publications/bmbl5/index.htm or the Public Health Agency of Canada at: http://www.phac-aspc.gc.ca/lab-bio/res/psds-ftss/index-eng.php#

Agent (genus and species)	Agent Risk Group	Biosafety Level

3. Agent characteristics (Fill Applicable Sections)
   a. Pathogenicity:
      (i) Is the agent a human pathogen? ☐ Yes ☐ No
      (ii) Susceptible host(s): _____
      (iii) Describe Pathogenicity:

      (iv) Virulence (i.e. infectious dose):

(v) Route(s) of Transmission:

(vi) Environmental stability:

(vii) Agent Countermeasures:

(viii) Describe the method of decontamination/disposal:

XIV. BIOLOGICAL TOXINS OR HAZARDOUS CHEMICALS

1. My activity involves hazardous chemicals or biological toxins (Toxins, carcinogens, mutagens, teratogens of proven or potential hazard eliciting serious chronic or acute effects in humans, other animals, or plants and requiring special handling precautions to prevent exposures)
   ☐ Yes ☐ No **(If "No", you may skip to Section XV)**
2. Name the chemical or toxin and briefly describe the nature. (For example: Carcinogens, Mutagens, Teratogens, Toxins, etc.)

3. Please describe the administration route (IV, IM, IP SubQ etc.) and the highest concentration of the hazardous chemical or toxin that will be administered

4. Will the hazardous chemical or toxin be administered to:
   ☐ Microbe
   ☐ Organ, Tissue, Cell Culture, Clinical Specimens
   ☐ Organism
5. Chemical or Toxin LD_{50}: _____

6. Please describe the method of decontamination/disposal:

XV. HUMAN BLOOD, BODILY FLUIDS, TISSUES OR CELL LINES *(BOTH HUMAN AND ANIMAL)*

1. My activity involves the use of:
   - ☐ Blood
   - ☐ Bodily Fluid
   - ☐ Tissues
   - ☐ Cultured Human Cell Lines
   - ☐ Cultured Animal Cell Lines

   If "No", you may skip to section XVI
2. Are the laboratory members enrolled in the UND Bloodborne Pathogens Exposure Control Plan. (https://und.edu/finance-operations/_files/docs/6-27-bloodborne-pathogens-ecp.pdf) - If working with human blood, bodily fluids, tissues or human cell lines

   ☐ Yes ☐ No ☐ N/A

FOR ENROLLMENT IN THE UND BLOODBORNE PATHOGENS EXPOSURE CONTROL PLAN:

- Please fill the Appendix 1 and Appendix 4 of the Policy (https://und.edu/finance-operations/_files/docs/6-27-bloodborne-pathogens-ecp.pdf) and submit a copy to the Office of Safety.

3. Source of blood, tissue or bodily fluid (e.g. Hospital, University, Commercial Vendor).
4. Indicate how the blood, bodily fluids, or tissues will be transported to UND.

5. Please describe the use of and infectious potential of blood, bodily fluids or tissues used in this project?

6. If your research activity involves the use of cell lines **(human or animal)**, please answer the questions below:

Cell line	**Technical Name (e.g. NIH3T3, Hep2)**	**Passage (primary established, immortal)**	**Administered to animals *in vivo* (Yes/No)**	**Recipient of rDNA construct (Yes/No)**	**Recipient of Microbe (Yes/No)**	**Recipient of Chemical (Yes/No)**

For primary human cell lines, provide the source and whether or not the cell lines are screened for any pathogens.

Cell line/Tissue	**Source**	**How Screened? For which pathogens?**

7. Please describe the method of disinfection/disposal.

8. Bloodborne pathogens training is required for all research team members that will be working with the human blood, bodily fluids, tissues or human cell lines. The Hepatitis B Vaccine series is available to personnel who have routine exposure to bloodborne pathogens (UND Bloodborne Pathogens Exposure Control Plan: https://und.edu/finance-operations/_files/docs/6-27-bloodborne-pathogens-ecp.pdf).

Please list study team members and date of bloodborne pathogen training in table

NAME	TRAINING DATE	HEPATITIS B SERIES OFFERED (Y/N)

XVI. ARTHROPOD USAGE:

1. My activity involves arthropods
   ☐ Yes ☐ No **(If "No", you may skip to Section XVII)**
2. What species will be used?

3. What building and room(s) is the insectary located?

4. Determine the applicable arthropod containment level based on the Arthropod Containment Guidelines: http://online.liebertpub.com/doi/pdf/10.1089/153036603322163475
   ☐ ACL-1 ☐ ACL-2 ☐ ACL-3
5. Is the arthropod species already established in the locale:
   ☐ Yes ☐ No ☐ N/A
6. If the arthropod is exotic, explain the likelihood that the arthropod would become temporarily or permanently established in the event of accidental escape?

7. Would accidental release of the arthropod significantly increase the risks to humans and animals above that already in existence in the event of introduction of exotic pathogens in the area?

8. Could the arthropod be controlled or locally eradicated by traditional methods (e.g. spraying, trapping) in the event of escape?

9. Is the arthropod derived from an exotic subpopulation (strain, geographically distinct from) whose phenotype is known or suspected to vary in ways that could reasonably be expected to significantly increase its vector competence?

10. Describe the method of decontamination/disposal of arthropod waste

XVII. VERTEBRATE ANIMAL USAGE:

1. Will animals be used in this Registration document?
   ☐ Yes ☐ No **(If "No", you may skip to Section XVIII)**
2. Is your laboratory enrolled in the UND Occupational Health Plan (https://und.edu/finance-operations/_files/docs/6-28-occupational-health-plan.pdf)?
   ☐ Yes ☐ No ☐ N/A

FOR ENROLLMENT IN THE UND OCCUPATIONAL HEALTH PLAN:

- Please fill the Appendix B and Appendix C of the UND policy (https://und.edu/finance-operations/_files/docs/6-28-occupational-health-plan.pdf) and submit a copy to the Office of Safety. [Please make sure that Appendix C is in a sealed envelope].

3. Will more than one animal species be covered under this Registration Document?
   ☐ Yes ☐ No
4. What animal species will be used? (List below all animal species covered under this Registration Document)

   _____

   _____
5. What is the status of the Animal Care and Use Protocol?
   ☐ Approved (IACUC Number: _____) ☐ Pending Approval ☐ Preparing

6. Describe which building(s) and room(s) will be used for procedures?

7. Will the animals be transported from the centralized animal facility (example: CBR1, CBR2, Starcher etc.) to any laboratory at UND (including core facilities)?
   ☐ Yes ☐ No
   a. If Yes, Please outline the transportation protocol below:

8. Which Animal Biosafety Level (ABSL) is appropriate for this activity?
   ☐ ABSL-1 ☐ ABSL-2 ☐ ABSL-3 ☐ BSL-3 Ag
9. Animal Housing and Care:
   a. Describe special housing requirements, if any:

b. PPE required for daily animal care activities: check all that apply

☐ Gloves ☐ Disposable shoes covers ☐ Safety glasses ☐ Disposable gowns/coveralls/Lab coat
☐ Respirator (specific type) ☐ Other (additional PPE required? Provide details:

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

d. Will the animals be shedding the agent?

☐ Yes ☐ No Unknown (If "Yes" provide information on how the agent is shed and the expected duration)

10. Will the animals be necropsied?
☐ Yes ☐ No Unknown (If "Yes" provide information where the necropsy and the PPE required for the necropsy)

11. Indicate how the blood, bodily fluids, or tissues will be transported to the PI's laboratory from the centralized animal facility.

12. Sanitation and disposal:
    a. Describe handling, decontamination and/or disposal of potentially contaminated waste (infected carcasses, bedding, sharps, PPE, etc.):

XVIII. PLANT STUDIES

1. Will plants be used in any aspect of the research proposal?
   ☐ Yes ☐ No **(If "No", you may skip to Section XIX)**
2. If Yes, describe briefly how plants are used in this protocol)

3. Will biological materials be inserted/inoculated/introduced into the plant?
   ☐ Yes ☐ No (If "Yes", describe briefly)

4. List all plant species and research locations used in this protocol.

Plant Species (Include genus species or variety)	Has this plant been altered? How?	Location Research will be conducted	Greenhouse Y/N?

5. Training is required for all research team members working in a greenhouse facility. Please list study team members and date of training in table

NAME	TRAINING DATE

6. Describe the method of decontamination/disposal of biohazardous waste:

XIX. NANOMATERIALS

1. Does the project uses engineered nanomaterials?
   ☐ Yes ☐ No **(If "No", you may skip to Section XX)**

The CDC defines a technology as engineered nanotechnology only if it involves all of the following:

- Research and technology development involving structures with at least one dimension in the range of 1 to 100 nanometers (nm), frequently with atomic/molecular precision.
- Creating and using structures, devices, and systems that have unique properties and functions because of their nanometer-scale dimensions.
- The ability to control or manipulate on the atomic scale.

Refer to: https://www.cdc.gov/niosh/topics/nanotech/default.html)

2. If Yes, then please describe the nanomaterials and how they will be utilized.

3. Describe the method of decontamination/disposal of nanomaterial waste:

XX. EXPERIMENTAL LOCATION (APPLICABLE FOR ALL POTENTIAL BIOHAZARD SECTIONS)

Laboratory where the experiments will be conducted.

Building/Room	Describe room security	Describe storage security

XXI. BIOHAZARD HANDLING/MANIPULATIONS (APPLICABLE FOR ALL POTENTIAL BIOHAZARD SECTIONS)

1. Describe the types of biohazard agent manipulations planned.

2. Describe containment conditions you will implement.

3. Does your procedure for biohazard agent manipulation have potential to create aerosols?
☐ Yes ☐ No (If "Yes" complete the table below)

Specify activity that create aerosols	Describe mitigation measures to be used

4. Will you be using a biosafety cabinet or other containment device?
☐ Yes ☐ No (If "Yes" complete the table below)

Type of BSC (e.g. Class II)	Location of BSC (Room Number)	Date of Certification

5. PPE required for the biohazard agent manipulation: check all that apply
☐ Gloves ☐ Disposable shoes covers ☐ Safety glasses ☐ Disposable gowns/coveralls
☐ Respirator (specific type) ☐ UV Shield ☐ Lab Coats
☐ Other (additional PPE required?) Provide details:

XXII. DUAL USE RESEARCH

Overview: Despite its value and benefits, certain types of research conducted for legitimate purposes can be utilized for both benevolent and harmful purposes. Such research is called "dual use research." Dual use research of concern is a subset of dual use research defined as: "life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security." The United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern articulates the practices and procedures required to ensure that dual use research of concern is identified at the institutional level and risk mitigation measures are implemented as necessary. For more information about this Policy and other policies regarding dual use research of concern, visit the U.S. Government Science, Safety, Security (S3) website at: http://www.phe.gov/s3/dualuse.

Agents and toxins: The 15 agents and toxins listed in this Policy are subject to the select agent regulations (42 CFR Part 73, 7 CFR Part 331, and 9 CFR Part 121), which set forth the requirements for possession, use, and transfer of select agents and toxins, and have the potential to pose a severe threat to human, animal, or plant health, or to animal or plant products. It is important to note, however, that the Federal Select Agent Program does not oversee the implementation of this Policy or the March 2012 DURC Policy.

Avian influenza virus (highly pathogenic)
Bacillus anthracis
Botulinum neurotoxin

For the purposes of this Policy, there are no exempt quantities of botulinum neurotoxin. Research involving any quantity of botulinum neurotoxin should be evaluated for DURC potential.

Burkholderia mallei
Burkholderia pseudomallei
Ebola virus
Foot-and-mouth disease virus
Francisella tularensis
Marburg virus
Reconstructed 1918 Influenza virus
Rinderpest virus
Toxin-producing strains of *Clostridium botulinum*
Variola major virus
Variola minor virus
Yersinia pestis

1. Does any of your work involve any of the agents above?
   ☐ Yes ☐ No
2. Does your work involve any of the experiments mentioned below?
   (Check all that apply to your activity or category of experiment)
   ☐ Render an immunization ineffective or disrupt immunity
   ☐ Confer to a pathogenic agent or toxin, resistance to clinically and/or agriculturally useful prophylaxes or therapeutics against that agent or toxin
   ☐ Enhance the pathogenic consequences of an agent or toxin
   ☐ Increase the capability of a pathogenic agent or toxin to be disseminated
   ☐ Alter the host range or tropism of a pathogenic agent or toxin
   ☐ Alter the susceptibility of a host population
   ☐ Generate a novel pathogenic agent or toxin, or reconstitute an eradicated pathogenic agent

NOTE: Link to NIH Office of Biotechnology Activities (OBA) Policy on Dual Use:
https://oir.nih.gov/sourcebook/ethical-conduct/special-research-considerations/dual-use-research

XXIII. ACCIDENTS, EXPOSURES, & EMERGENCY RESPONSE

1. In the event of an accident/potential exposure, do you agree to follow the procedures listed below?
   ☐ YES ☐ NO

Actions to take in the event of an exposure....

A. Flush the exposed area with water. If your eyes, nose or mouth were exposed to blood or other potentially infectious materials, flush these areas for 15 minutes. If your skin was exposed, thoroughly wash these areas with soap and water. Bandage the affected area if needed to control bleeding.

B. Notify your supervisor if he or she is available. The Supervisor/PI is responsible to submit the Incident Reporting form to Office of Safety (https://und.edu/public-safety/_files/docs/incident-reporting-form.pdf) and the IBC adverse event reporting form (https://und.edu/public-safety/_files/docs/ibc-adverse-event-report.pdf) to IBC within 24 hrs of the incident.

C. Report to the designated medical care provider as soon as possible for follow-up. Take any applicable biological material description documents with you as well.

D. For exposure incidents involving human-derived materials (i.e., human cells or blood products), report immediately to designated medical care provider. Identify yourself to staff as a UND employee/student who has had a bloodborne pathogens exposure. **[Refer to UND's Bloodborne Pathogens Exposure Control Plan** (https://und.edu/finance-operations/_files/docs/6-27-bloodborne-pathogens-ecp.pdf)**]**

E. For all other biological material exposures, report as soon as possible to the designated medical care provider.

F. For any accidents/exposures involving biohazardous materials, notify the Office of Safety (777-3341) as soon as possible. Both medical evaluation and safety practices follow-up must be completed and documented for such incidents per the provisions of CDC, NIH, and University of North Dakota policies.

XXIV. PERSONNEL. Identify all personnel conducting the experiments (including Students and Staff). Specify degree, project responsibilities, applicable training and experience including duration (e.g. 2 years). Current Biosafety Training is required for BSL-2 and BSL-3 disclosures. Biosafety training is NOT the same as Laboratory Safety training.

Participant Name	Degree	Project Responsibilities	Prior Experience or Training Related to Responsibilities	FOR IBC USE ONLY TRAINING VERIFICATION

1. Have all collaborators/workers been informed of any potential dangers associated with this activity and do you have documentation? (Having a signature sheet in the lab specific safety manual is a suggested form of documentation)
   ☐ Yes ☐ No

XXV. DATE/YEAR OF LAST LABORATORY SAFETY AUDIT: _____

1. Are all the Corrective Actions required by the Office of Safety been implemented by the laboratory:
   ☐ Yes ☐ No ☐ N/A

(Note: Corrective actions need to be implemented before approval of the IBC Registration Document)

INVESTIGATOR ASSURANCE FOR RESEARCH INVOLVING RECOMBINANT OR SYNTHETIC NUCLEIC ACID, INFECTIOUS AGENTS AND/OR HUMAN BLOOD/TISSUE/CELL LINES

(Print this page separately because it requires a signature by the PI)

Principal Investigator Name:_____

Title of Project: _____

_____

ASSURANCES BY THE PRINCIPAL INVESTIGATOR:

1. I agree to conduct this project in accordance with the compliance policies of University of North Dakota, including all training of project participants.
2. I have consulted Section IV-B-7 of the NIH Guidelines which describes the responsibilities of the Principal Investigator and hereby agree to comply fully with all provisions of the Guidelines.
3. I understand that any proposed changes or modifications to an approved Registration Document (e.g. changes in the source of DNA, host-vector system, infectious agent, etc.), or in project participants must be submitted to, and approved by the Institutional Biosafety Committee (IBC) prior to execution.
4. If funded by an extramural source, I assure that this application accurately reflects all procedures involving Recombinant DNA, Infectious Agents and/or Tumorigenic Material described in the grant proposal to the funding agency.
   I understand that I have a responsibility to promptly report accidents (loss of containment, illness, biological material release/escape etc.) associated with my activity to the appropriate entities, i.e. Institutional Biosafety Committee, Biological Safety Officer, and the Office of Safety. etc.
   [Incident Report forms are located at: https://und.edu/public-safety/resources/forms.cfm and IBC Adverse Event Reporting Form is located on the IBC webpage: https://und.edu/research/resources/institutional-biosafety-committee.cfm].
5. The information within this application is accurate to the best of my knowledge.

_____ _____

Signature of Principal Investigator **Date**

The IBC/Office of Safety reserves the right to conduct inspections of the research facilities at any time.

Please return the completed form to:
UND.ibc@UND.edu