**FOR OFFICE USE ONLY: IBC PROTOCOL # _____ STATUS: _____**
**ANIMAL WORK: _____CONTAINMENT BSL: _____RECOMBINANT DNA: _____**
**TRAINING COMPLETE: _____**

# University of North Dakota
# Institutional Biosafety Committee (IBC)
# Instructional 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.

**Instructional Registration Documents are approved for a period of 3 years. Continued activity past 3 years will require a new Registration Document to be submitted. Submitting a Modification is Not a Renewal of an existing Instructional Registration Document.**

The University of North Dakota (UND) Institutional Biosafety Committee (IBC) has university oversight responsibility for reviewing and approving all activities that involve the use of recombinant DNA or infectious/tumorigenic materials or biological research. Consequently, it is critical that the IBC receive sufficiently detailed information to fulfill its review and approval mandate. This IBC Instructional 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 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 instructional activity involving recombinant DNA and/or infectious agents, as described in the National Institutes of Health (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!

If you need help or have questions about how to complete this application, please contact the IBC Chair, Matthew Nilles, at matthew.nilles@med.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**

## I. ADMINISTRATIVE INFORMATION:

| | | | |
|---|---|---|---|
| **Title of Course:** | | | |
| **Course number:** | | | |
| **Instructor:** | | | |
| **Degree/Title:** | | | |
| **Department:** | | **Phone No:** | |
| **Building, Office Room No., Mail Code** | | **Email:** | |
| **Co-Instructor:** | | | |
| **Degree/Title:** | | | |
| **Department:** | | **Phone No:** | |
| **Building, Office Room No., Mail Code** | | **Email:** | |
| **Semester Taught:** | | | |
| **Room Course is Taught in:** | | | |

## II. MODIFICATION

**Is this a modification of an approved Instructional Registration Document? (Submitting a modification is NOT a renewal of an existing Instructional Registration Document)**

☐ No (Go to Section III) ☐ Yes (If "Yes", please list document # _____ and comply with the following):

If you are requesting a modification or a change to an IBC approved Instructional Registration Document, please provide a concise description of all the changes that you are proposing in the following block. This will greatly help the committee and facilitate this review.

## 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
  https://und.edu/research/resources/institutional-biosafety-committee.cfm
- ☐ Arthropods
- ☐ Vertebrate Animal Usage
- ☐ Plant Studies
- ☐ 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 Instructional Registration Document.***

## IV. RISK ASSESSMENT

Have you performed a risk assessment for the proposed instructional 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. BIOSAFETY MANUAL

***"Each laboratory should develop or adopt a biosafety or operations manual that identifies the hazards that will be encountered, and that specifies practices and procedures designed to minimize or eliminate exposures to these hazards. Personnel should be advised of special hazards and should be required to read and follow the required practices and procedures".*** **(BMBL, 5th Edition, Section III, Page 32, Laboratory Practice and Techniques).**

**Identify all categories that have been completed:**

- ☐ Key Personnel: (provide roster, current contact information for all key personnel, i.e. phone#, etc.)
- ☐ Identification of Biological/rDNA agent in use
- ☐ Identification of containment (Biosafety) Level Assigned
- ☐ Biological Agent Information (Agent Fact Sheet)
- ☐ Targeted Occupational Health Information
- ☐ Safety and Security/Standard Operating Procedures (SOPs): (Biosafety Manual should include copies of applicable SOPs for things like decontamination, waste disposal, security, emergency procedures, handling procedures, etc.)

**NOTE: A Template for *Laboratory Specific Biosafety Manual* can be found on the Office of Safety website** (http://und.edu/public-safety/public-safety/biological.cfm).

- ☐ Emergency Specific Procedures (Biosafety Manual should list procedures to be followed in case of an accident such as a spill, injection, ingestion, aerosolization, splash etc.)
- ☐ Emergency Notification: (Campus Police, Office of Safety, Emergency Medical Personnel, etc.)
- ☐ Signature Sheet
- ☐ Training Records

## VI. COMPLIANCE CHECKLIST

**Does the instructional activity 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 for select agent use (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. BIOHAZARD AGENT INFORMATION (Answer both questions in this section)

1. Do you currently possess the agent/organism that is intended for use in this Instructional Registration Document?
   ☐ Yes ☐ No
2. Provide the source of the agent/organism that will be used in this activity:

## VIII. PROJECT DESCRIPTION: Provide a succinct narrative of the laboratory exercises or experimental protocol proposed involving recombinant or synthetic nucleic acid, infectious agents, and/or Human Blood/Tissue/Cell lines. Provide enough detail for the committee to evaluate the containment level required.

## 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:**_____

**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 instructional 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.

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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.)

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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.

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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.

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

## XI. VIRUSES AND VIRUS VECTORS

1. My proposed instructional 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)

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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)

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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)

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

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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?)

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

1. My instructional 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 |
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3. Sanitation and Disposal:
   a. Describe handling, decontamination and or disposal of potentially contaminated waste:

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## XIV. BIOLOGICAL TOXINS OR HAZARDOUS CHEMICALS

1. My instructional 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.)

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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

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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:

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

1. My instructional activity involves the use of:
   ☐ Blood
   ☐ Bodily Fluid
   ☐ Tissues
   ☐ Cultured Cell Lines ((Human or Animal Cell Lines - Go to Question 5)
   (If "No", you may skip to section XVI)
2. Are the students enrolled in the UND Bloodborne Pathogens Exposure Control Plan (https://und.edu/finance-operations/_files/docs/6-27-bloodborne-pathogens-ecp.pdf) – Enrollment needed only If working with human blood, bodily fluids, tissues or human cell lines
   ☐ Yes ☐ No ☐ N/A
3. Source of blood, tissue or bodily fluid (e.g. Hospital, University, Commercial Vendor).

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4. Indicate how the blood, bodily fluids, or tissues will be transported to UND.

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

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6. If your research activity involves the use of cell lines, 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) |
|---|---|---|---|---|---|---|
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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? |
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7. Please describe the method of disinfection/disposal.

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8. Bloodborne pathogens training is required for all research team members that will be working with the blood, bodily fluids, tissues or human cell lines. The Hepatitis B Vaccine series is available to personnel who have routine exposure to bloodborne pathogens.

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

| NAME | TRAINING DATE | HEPATITIS B SERIES OFFERED (Y/N) |
|---|---|---|
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## XVI. VERTEBRATE ANIMAL USAGE:

1. Will animals be used in this Instructional Registration Document?

☐ Yes ☐ No (If "No", you may skip to Section XVII)

2. Are the students enrolled in the UND Occupational Health Plan (https://und.edu/finance-operations/_files/docs/6-28-occupational-health-plan.pdf)? – Enrollment is based on risk assessment for instructional activity
   ☐ Yes ☐ No ☐ N/A
3. What animal species will be used?
   _____
4. What is the status of the Animal Care and Use Protocol?
   ☐ Approved (IACUC Number: _____) ☐ Pending Approval ☐ Preparing
5. What building(s) and room(s) will be used?
   _____
6. Which Animal Biosafety Level (ABSL) is appropriate for this activity?
   ☐ ABSL-1 ☐ ABSL-2 ☐ ABSL-3 ☐ BSL-3 Ag
7. PPE required for daily animal care activities: check all that apply
   ☐ Gloves ☐ Disposable shoes covers ☐ Safety glasses ☐ Disposable gowns/coveralls
   ☐ Respirator (specific type) ☐ Other (additional PPE required? Provide details_____
   _____
8. Sanitation and disposal:
   a. Describe handling, decontamination and/or disposal of waste (bedding, sharps, PPE, etc .):

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## XVII. PLANT STUDIES

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

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

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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? |
|---|---|---|---|
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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 |
|---|---|
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## XVIII. EXPERIMENTAL LOCATION (APPLICABLE FOR ALL POTENTIAL BIOHAZARD SECTIONS)

Laboratory where the experiments will be conducted.

| Building/Room | Describe room security | Describe storage security |
|---|---|---|
| | | |
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## XIX. BIOHAZARD HANDLING/MANIPULATIONS (APPLICABLE FOR ALL POTENTIAL BIOHAZARD SECTIONS)

1. Describe the types of biohazard agent manipulations planned.

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2. Describe containment conditions you will implement.

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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 |
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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 |
|---|---|---|
| | | |
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## XX. SAFETY MEASURES (APPLICABLE FOR ALL POTENTIAL BIOHAZARD SECTIONS)

**Indicate Personal Protective Equipment (PPE) planned for the activity and who will provide the PPE (i.e. students or instructors):**

☐ Lab Coats _____

☐ Safety Glasses_____

☐ Closed Toe Shoes_____

☐ Gloves_____

☐ Other _____

## XXI. 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 and the IBC Adverse Event Reporting form 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]**

**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**.**

**INSTRUCTOR 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 Instructor)

**Instructor Name:**_____

**Title of Project:** _____

_____

**ASSURANCES BY THE INSTRUCTOR:**

1. I agree to conduct this instructional activity 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 Instructor and hereby agree to comply fully with all provisions of the Guidelines.
3. I understand that all changes in the instructional protocol (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. I understand that I have a responsibility to promptly report accidents (loss of containment, illness, etc.) associated with my activity to the appropriate entities, i.e. IBC, Biological Safety Officer, and Office of Safety. etc.
   **NOTE:** Incident Report forms are located at: https://und.edu/public-safety/resources/forms.cfm. IBC Adverse Event Reporting Form is located on the UND 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 Instructor** **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**