

(Added by IBC) Date Approved: (Added by IBC) Protocol #:

|  |
| --- |
| **NAU Institutional Biosafety Committee Protocol Registration Form** |

* Please describe all work with [biohazardous materials](https://www.research.vt.edu/ibc/biohazardous-agent-defined0.html) (including rDNA and synthetic nucleic acids placed in a biological system) to be conducted by a Principal Investigator (PI). It may cover multiple projects as long as all the work (e.g. biological materials, personnel, & locations) are similar and all the procedures involving biohazardous materials are described comprehensively.
* Contact the Biological Safety Office at [biosafety@nau.edu](mailto:biosafety@nau.edu), (928) 523-7268/(928) 523-4782 for assistance.
* Submit the completed application electronically to [biosafety@nau.edu](mailto:biosafety@nau.edu). Retain a copy of your completed application for your records.

|  |
| --- |
| **Section 1: General Information** |

Principal Investigator:       Title:

Department:       Campus Address:

Primary Work Phone Number #:       Email:

Laboratory Contact:       Title:

Department:       Campus Address:

Primary Work Phone Number:       Email:

|  |  |
| --- | --- |
| Project Title:  Location of Project Bldg. Number:  Project Room(s): | Will animals\* be used?  Yes  No  Housing & Procedure Room(s):  IACUC Protocol Number:  Approval Date: |
| **Will human subjects be used?**  Yes  No  IRB Protocol Number:  Approval Date: | **Will isotopes be used?**  Yes  No  RSC Protocol Number:  Approval Date: |

\* If using or creating transgenic animals, please complete the rDNA – Transgenic Animals Registration Form

**Project Funding Status (check all that apply):**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Status** | **Name of Granting Agency**  **(or other source)** | **Title of Award** |
|  | Fully or partly funded by federal grant |  |  |
|  | Pending funding by federal grant |  |  |
|  | Funding to be provided by NAU |  |  |
|  | Funding provided by other organization |  |  |

|  |
| --- |
| **Section 2: Biological Agents, Toxins, or Plants** |

List each agent and the [biosafety level/risk](https://my.absa.org/tiki-index.php?page=Riskgroups) group associated with it.

|  |  |
| --- | --- |
| Agent (genus, species, & common name, if applicable) | Biosafety Level/Risk Group |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |

|  |
| --- |
| **Section 3: Description of Project** |

Provide a brief description and overview of your research goals and objectives involving biohazardous agents, recombinant DNA (rDNA), and/or synthetic nucleic acids placed in a biological system. This should be the general area under study, not the detailed experimental methods; however, sufficient information must be presented so that the IBC may understand the general scope of the work. Research descriptions should be readily comprehensible by a lay-person and free from technical jargon (unless unavoidable; then briefly define/describe the term). Include overall objectives, the source(s) of biological material, describe host(s) and vector(s) to be used. If research involves rDNA: what is the nature of the inserted DNA sequences (genetic modification); will a deliberate attempt by made to express a foreign gene; indicate the protein or transcript that will be produced. **Attach any relevant manuals, SOPs, and reference materials.**

Standard operating procedures (SOPs) for safe handling of your research materials should include:

* Identification of potential personnel exposure hazards during sample preparation and experimental manipulations (e.g., aerosol generation when transferring, mixing, or centrifuging, use of sharps, excretion by animals, etc.).
* Safety procedures that will be employed to minimize the risk of exposure and prevent release of infectious agents (e.g. protective clothing, use of biological safety cabinet, sharps disposal procedures, waste disposal procedures, etc.).
* Accidental spill/exposure procedures.

|  |
| --- |
|  |

|  |
| --- |
| **Section 4: Scope of Research** |

1. \*If you answer ‘yes’ to any question below, please fill out a Health Hazard Assessment for the agent(s), the Biological Safety Office is available for assistance\*.

A) Will you manipulate a naturally occurring pathogen(s), one that has not been altered by rDNA, which is infectious to humans, animals, or plants?

Yes  No

B) Will you work with non-human primate body fluids, tissues, or cell cultures?

Yes  No

C) Will you work with human body fluids, human tissues, and/or human cell cultures?

Yes  No If yes, please describe:

If yes, have the researchers been registered in the bloodborne pathogen program?

Yes  No

If yes, please provide the names of personnel:

1. Will you acquire, store, generate, or manipulate animal (other than human and non-human primate) cells and/or tissue samples?

Yes  No

1. Will you acquire, store, generate, or manipulate any regulated agents, select agents, and/or biotoxins?

Yes  No

1. Permits and Licenses:

A) If your project will involve a human pathogen or human material that originated outside of the USA,

a CDC Etiologic Agent Import Permit may be required. Please visit their [website](http://www.cdc.gov/od/eaipp/) for information.

B) If your project uses infectious agents of livestock and biological materials containing animal material, a USDA/APHIS permit may be required. Visit their [website](http://www.aphis.usda.gov/permits/index.shtml).

C) U.S. Fish and Wildlife Service permits are required for certain live animals, including bats. Visit their [website](http://www.fws.gov/permits/ImportExport/ImportExport.html) or call 1-800-344-WILD for more information.

D) If your project will involve the import of [select agents and toxins](https://www.selectagents.gov/), you must be registered with CDC’s Select Agent Program. Contact the NAU BSO, Shelley Jones, for more information.

E) If your project will involve the export of a wide variety of etiologic agents of human, plant, and animal diseases, a license from the Department of Commerce may be required. Visit their [website](http://www.bis.doc.gov/licensing/index.htm) or call (202) 482-4811 for more information.

F) If the appropriate permit(s) have already been obtained, please list the applicable permit numbers:

|  |
| --- |
| **Section 5: Biosafety Considerations & Procedures** |

|  |  |
| --- | --- |
| Biosafety cabinet:  Yes  No  Model:  Location:  Certification date: | Autoclave available:  Yes  No  Location:  QA/QC monitored by: |
| Personal protective equipment used (list):    Method of inactivation of agent(s):    Disinfection of surfaces procedure: | How do you dispose of biohazardous waste?    Are Standard Operating Procedures (SOPs) prepared for work with the agent(s)?  Yes  No  *Please submit all relevant SOPs with this registration form*.  Hand washing sink available?  Yes  No |

1. Will you work with biological agents with/in any of the following aerosol-producing devices/procedures?

Centrifuges  Vortexers  Shakers

Sonicators  Tissue homogenizers  Infected animal necropsy

Intranasal inoculation  Pressurized vessels  Large volumes (≥ 10L)

of animals (besides autoclaves) of infectious material

Flow Cytometer  Electroporator

1. Have staff received immunizations and/or tests for agents in use or that are potentially present in the lab (e.g. hepatitis B vaccine, Vaccinia vaccine, TB skin testing)?

Yes  No If yes, please list:

1. Will the protocols require the use of sharps, such as, but not limited to, needles, scalpels, and/or razor blades?

Yes  No If yes, please visit the EHS website to learn more about the NAU Needlestick

Safety and Prevention Program, then complete the evaluation form(s) as necessary.

|  |
| --- |
| **Section 6: NIH Regulated Recombinant DNA and Synthetic Nucleic Acids Molecules Research** |

The NIH guidelines define recombinant and synthetic nucleic acids as:

1. Molecules that are constructed by joining nucleic acid molecules and can replicate in a living cell (i.e. recombinant nucleic acids);
2. Nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acids (i.e. synthetic nucleic acids).
3. Molecules that result from the replication of those described in (i) or (ii) above.

A) My research does not involve rDNA or synthetic nucleic acids placed in a biological system.

If checked, proceed to Section 7

B) My research does involve rDNA or synthetic nucleic acids placed in a biological system. (This includes plasmids, viral vectors, creation of transgenic organisms, gene therapy, etc.)

If checked, complete the rest of Section 6

Please select the classification for each type of recombinant/synthetic nucleic acid research performed in your laboratory below. Use the EH&S online [NIH Guidelines rDNA Training](https://nau.edu/nau-research/research-safety-and-compliance/environmental-health-and-safety/safety-programs/biological-safety/) and/or the [NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules](https://osp.od.nih.gov/biotechnology/biosafety-and-recombinant-dna-activities/) to help classify your research.

**Section III-A-1-a:**The deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally (see Section V-B, Footnotes and References of Sections I-IV), if such acquisition could compromise the ability to control disease agents in humans, veterinary medicine, or agriculture, will be reviewed by the RAC. (Requires NIH OSP and IBC approval before research may begin).

**Section III-B-1:** Experiments involving the cloning of toxin molecules with LD50 of less than 100 ng/kg of body weight (Requires NIH OSP and IBC approval before research may begin).

**Section III-C-1:** Experiments involving the deliberate transfer of recombinant or synthetic nucleic acid molecules, or DNA or RNA derived from recombinant or synthetic nucleic acid molecules, into one or more human research participants (Requires NIH OSP and IBC approval before research may begin).

**Section III-D-1:** Experiments using Risk Group 2, Risk Group 3, Risk Group 4, or restricted agents as host-vector systems. Please select risk group below:

Risk Group 2 (RG2): Agents are associated with human disease which is rarely serious and for which preventative or therapeutic interventions are often available.

Risk Group 3 (RG3): Agents are associated with serious or lethal human disease for which preventative or therapeutic interventions may be available.

**Section III-D-2:** Experiments in which DNA from Risk Group 2, Risk Group 3, or restricted agents is cloned into nonpathogenic prokaryotic or lower eukaryotic host-vector systems. Please select risk group below:

Risk Group 2 (RG2): Agents are associated with human disease which is rarely serious and for which preventative or therapeutic interventions are often available.

Risk Group 3 (RG3): Agents are associated with serious or lethal human disease for which preventative or therapeutic interventions may be available.

**Section III-D-3:** Experiments involving the use of infectious DNA or RNA viruses or defective DNA or RNA viruses in the presence of helper virus in tissue culture systems.

Risk Group 2 (RG2): Agents are associated with human disease which is rarely serious and for which preventative or therapeutic interventions are often available.

Risk Group 3 (RG3): Agents are associated with serious or lethal human disease for which preventative or therapeutic interventions may be available.

**Section III-D-4:** Experiments involving whole animals that cannot be done at BSL-1

**Section III-D-5:** Experiments involving whole plants; Experiments to genetically engineer plants by recombinant or synthetic nucleic acid molecule methods, to use such plants for other experimental purposes (e.g. response to stress), to propagate such plants, or to use plants together with microorganisms or insects containing recombinant or synthetic nucleic acid molecules that cannot be done at BSL-1.

**Section III-D-6**: Experiments involving more than 10 liters of culture.

**Section III-D-7:** Experiments involving Influenza viruses.

**Section III-E-1:** Experiments involving the formation of recombinant or synthetic nucleic acid molecules containing no more than 2/3 of the genome of any eukaryotic virus (BSL-1 experiments only).

**Section III-E-2:** Experiments involving recombinant DNA-modified whole plants, and /or experiments involving recombinant or synthetic nucleic acid molecule-modified organisms associated with whole plants, except those that fall under Section III-A, III-B, III-D, or III-F (BSL-1 experiments only).

**Section III-E-3:** Experiments involving transgenic rodents modified by the stable introduction of recombinant or synthetic nucleic acid molecules into their genome, or nucleic acids derived therefrom, into the germ-line (transgenic rodents). (BSL-1 experiments only).

**NIH Exempt Experiments (subject to review by the IBC Chair and Biological Safety Officer):**

**Section III-F-1**: Experiments using synthetic nucleic acids that: (1) can neither replicate nor generate nucleic acids that can replicate in any living cell, (2) are not designed to integrate into DNA, and (3 do not produce a toxin that is lethal for vertebrates at an LD50 of <100 ng/kg.

**Section III-F-2:** Recombinant/synthetic molecules are not in organisms, cells, or viruses, and that have not been modified or manipulated to make cellular membrane penetration possible.

**Section III-F-3**: Recombinant/synthetic molecules that consist entirely of the exact recombinant or synthetic nucleic acid sequence from a single source that exists in nature.

**Section III-F-4:** Recombinant/synthetic molecules that consist entirely of DNA from a prokaryotic host including its indigenous plasmids, or viruses when propagated only in that host (or closely related strain of the same species), or when transferred to another host by well-established physiological means.

**Section III-F-5:** Recombinant/synthetic molecules that consist entirely of DNA from an 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).

**Section III-F-6:** Those that consist entirely of DNA segments form different species that exchange DNA by known physiological processes, though one or more of the segments may be a synthetic equivalent. A list of such exchangers is prepared and periodically revised by the NIH Director and can be found in the [NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf).

**Section III-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.

**Section III-F-8:** Those exemptions as determined by the NIH Director to not present a significant risk to health or the environment are listed in the appendices below. Please check all categories that apply:

Appendix C-I: Recombinant or synthetic nucleic acid molecules in tissue culture.

Appendix C-II: Escherichia coli K-12 host-vector systems.

Appendix C-III: Saccharomyces host-vector systems.

Appendix C-IV: Kluyveromyces host-vector systems.

Appendix C-V: Bacillus subtilis or Bacillus licheniformis host-vector systems.

Appendix C-VI: Extrachromosomal elements of gram positive organisms.

Appendix C-VII: The purchase or transfer of transgenic rodents.

Appendix C-VIII: Generation of BL1 transgenic rodents via breeding.

|  |  |
| --- | --- |
| **Recombinant or Synthetic Nucleic Acid Molecules Project Summary** | |
| 1. Does this research involve “the deliberate transfer of a drug resistance trait to microorganisms if such acquisition could compromise the ability to treat or manage disease agents in human and veterinary medicine, or agriculture?”  Yes  No   If yes, explain: | 1. Will the research involve the use of antibiotic selection markers?  Yes  No   If yes, list the markers and the microbial agents used (e.g., kanamycin resistance marker in E. coli). |
| 1. Are you increasing the pathogenicity of a pathogen?  Yes  No   If yes, explain: | 1. Will you be working with >10 liters of recombinant material?  Yes  No   If yes, explain: |
| 1. Are you working with genetic material coding for a vertebrate toxin as defined in the [NIH Guidelines](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf)?  Yes  No   If yes, explain: | 1. List all cell lines to be used in the research, including the source species (Note that work with human or primate cell lines requires BSL2 containment.): |
| 1. Will you use plants, including plant parts, or plant cell lines?  Yes  No   If yes:  Will you use commercially available, de-regulated transgenic plants only?  Yes  No  Will biological materials be inserted/inoculated/introduced?  Yes  No | |
| 1. Purpose of the project (one sentence): | |
| 1. Project goals/intent: | |
| 1. Expected outcome: | |
| 1. What will be analyzed or measured? | |
| 1. What effect would transgene expression have in an accidental host? | |
| 1. What are possible safety hazards associated with the recombinant/synthetic nucleic acid molecules component of this project, and how will you address them? Please attach your SOP (components described below). | |
| 1. Vector Information – Gene transfer will involve (check a, b, c, or appropriate combination): 2. Physical methods (e.g. pronuclear injection, electroporation, “gene gun”, etc.). Describe:      1. Host-Vector System (describe each host-vector system utilized in the project) 2. Is the host-vector system commercially available?  Yes  No   Source Vendor:     1. Have you made any modifications to the system?  Yes  No   If yes, please describe:     1. If host-vector system is viral, will you be making viral particles?  Yes  No 2. If host-vector system is viral, will you be conducting serial passages of viral particles?  Yes  No   If yes, what cell line will you be using?    Non-commercial vectors, please describe (include the source, the number of plasmids for the vector system, any information on serial passaging of viral particles and cell lines used):    **Attach a detailed map of all vectors to be used.** Please indicate any regions that increase the safety of this construct. Provide copies of key references that describe the construction of the vector(s) to be used. You can use PDF files or submit hard copies attached to this form.  Are human, animal, insect, or plant pathogens used as host-vector systems?  Yes  No   1. Other (e.g. conjugation, etc.). Describe: | |
| 1. Gene/Insert Information - List genes to be transferred, please explain any abbreviations:  |  |  | | --- | --- | | **Gene** | **Species of Origin** | |  |  | |  |  | | |

|  |
| --- |
| **Section 7: Dual Use Research of Concern (DURC)** |

1. Does your research involve one or more of the agents or toxins listed below?  Yes  No

* Avian influenza virus (highly pathogenic)
* Bacillus anthracis
* Botulinum neurotoxin
* Burkholderia mallei
* Burkholderia pseudomallei
* Ebola virus
* Foot-and-mouth disease virus
* Francisella tularensis
* Marburg virus
* Toxin-producing strains of Clostridium botulinum
* Variola major virus
* Variola minor virus
* Yersinia pestis

1. Please indicate whether your research project produces, aims to produce, or can be reasonably anticipated to produce any of the following experimental effects. The IRE should review descriptions of the research in question, the PI’s assessment of the applicability of the categories of experiments, and other relevant information, as warranted. Examples of materials to consider include the project proposal, any project reports, any outcomes of previous reviews for dual use, and examples of similar research in the literature.

* Enhances the harmful consequences of the agent or toxin  Yes  No
* Disrupts immunity or the effectiveness of an immunization against the agent or toxin withour clinical or agricultural justification  Yes  No
* Confers to the agent or toxin resistance to clinically or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitates their ability to evade detection methodologies  Yes  No
* Increases the stability, transmissibility, or the ability to disseminate the agent or toxin

Yes  No

* Alters the host range or tropism of the agent or toxin  Yes  No
* Enhances the susceptibility of a host population to the agent or toxin  Yes  No
* Generates or reconstitutes an eradicated or extinct agent or toxin listed above in Question 1

Yes  No

1. If you checked yes for any of the experimental effects listed in Question 2, please provide more information:

|  |
| --- |
| **Section 8: Personnel** |

Identify all personnel that will be involved in the project described above. By signing, they agree that they are familiar with and agree to abide by the current NAU and federal guidelines.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Name | [NIH Guidelines](https://nau.edu/nau-research/research-safety-and-compliance/environmental-health-and-safety/safety-programs/biological-safety/) Training Date | [Biosafety](https://nau.bioraft.com/raft/training/courses) Training Date | Bloodborne Pathogens Training Date (if applicable) | BBP Hepatitis B Vaccination Status  (Circle One, if applicable) | Shipping & Transport of Biohazardous Materials  (if needed; every 2 years) | Signature | Date Signed |
|  |  |  |  | Declination form or vaccine records attached |  |  |  |
|  |  |  |  | Declination form or vaccine records attached |  |  |  |
|  |  |  |  | Declination form or vaccine records attached |  |  |  |
|  |  |  |  | Declination form or vaccine records attached |  |  |  |

Note: the employer (NAU) must have a copy of Hepatitis B vaccination records or a signed declination form, as required by OSHA. Please include the appropriate documentation with your application (if not already on file with EHS).

|  |
| --- |
| **Section 9: Principal Investigator’s Acknowledgement of Responsibilities** |

By signing below, I agree that I and all listed personnel on my IBC protocol and amendments will abide by the statements, and all policies and procedures governing the use of infectious agents, recombinant DNA, and other biohazardous materials, as outlined by NAU policies and applicable federal regulations. I am responsible for:

* + ensuring the information provided in this application is complete and accurate.
  + obtaining approval from the IBC before proceeding with rDNA or biohazardous work.
  + ensuring that anyone who enters my laboratory practices appropriate biosafety precautions.
  + ensuring that all listed participants have received appropriate training in safe laboratory practices before beginning work on this project.
  + ensuring that anyone working in or having access to spaces where this project is conducted is instructed on the hazards associated with this project (IBC or EHS staff will review records documenting the training or instruction of personnel).
  + complying with the requirements pertaining to the shipment and transfer of biohazardous materials, including permits.
  + reporting to the Biosafety Officer immediately any spill of biohazardous material, containment equipment failure, and/or any deviation in procedures, which may result in potential exposure of laboratory personnel and/or the public to biohazardous material.
  + reporting to the Biosafety Officer immediately should an employee become ill and/or exhibit symptoms and signs consistent with an infection caused by an organism associated with my research.
  + following all the applicable guidelines as approved for this protocol.
  + submitting in writing a request for approval from the IBC of any significant modifications to the protocol.

Electronic Signature of the Principle Investigator:        Date:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| By typing your name you are submitting an electronic signature that confirms your understanding and adherence to the above statements and IBC policies. | | | | | |
|  |  |  |  |  |  |