## ncsu1 AMENDMENT #     to BIOLOGICAL USE AUTHORIZATION

 *Form* *Revised 05/2023*

*EHS Use Only*

**IBC #:      IBC Approval Date:**

**Date Received:**       **NIH Classification(s):**

**BUA Complexity Rating:** Low/Moderate/High **Containment Level(s):**

**EHS Comments:**

*EHS Use Only*

**Do I need to submit an Amendment?** In the table below, check the box in the Type of Change column. *Check all that apply.* Follow the instruction in the corresponding column and submit an Amendment as necessary. It is helpful to reference your original approval(s) when completing this table. If your modification is not listed in the table below, contact EHS Biosafety at (919) 515-6858.

|  |  |  |
| --- | --- | --- |
| **Type of Change** | **Do I Submit Amendment?** | **Instruction** |
| [ ]  | Addition of personnel *only* | No | Add new workers to the Statement of Informed Consent in the original approval.  |
| [ ]  | Addition of laboratory space *only* for work already approved by IBC | No | Email the Biosafety Officer with your changes in location and the anticipated biosafety level for your new space.  |
|  |  *Containment* |  |  |
| [ ]  | Increasing containment level from BSL-1 to BSL-2 *or* from BSL-2 to BSL-3  | Yes | Complete Part B and describe in **Narrative** |
| [ ]  | Change in containment practices at BSL-2 | Yes | Describe changes in PPE, practices, transport, equipment in **Narrative** |
|  |  *Agents/Organisms* |  |  |
| [ ]  | Change in use of recombinant or synthetic nucleic acid molecules | Yes | Complete **Part C** and describe change in **Narrative** |
| [ ]  | Change in use of genetically modified Plants or Animals | Yes | complete **Part C** and describe change in **Narrative** |
| [ ]  | Change in use of organisms associated with disease in humans, animals, or plants | Yes | complete **Part D** and describe change in **Narrative** |
| [ ]  | Change in use of arthropods/drosophila | Yes | see **Part E** for exceptions to completing that Part and describe change in **Narrative** |
| [ ]  | Change in use of biological toxins | Yes | complete **Part G** and describe change in **Narrative** |
| [ ]  | Change in use of human or non-human primate body fluids, cell lines, or tissues | Yes | complete **Part H** and describe change in **Narrative** |
| [ ]  | Change in use of live vertebrate animals  | Yes | complete **Part F** and describe change in **Narrative** |

**Approval Process:** After the amendment is submitted per the directions below, EHS will conduct a pre-review of the form and notify the PI of omissions or the need for clarification. Incomplete fields, an incomplete Biosafety Narrative, or inaccurate information can result in significant delays in the processing of this form. The form will be forwarded to the Institutional Biosafety Committee to review for approval. Final IBC approval of amendment can take as little as two weeks or as long as several months depending on the type of amendment. For questions related to this form or the approval process, contact the Biosafety Section at Environmental Health & Safety (919-515-6858). For more information about the Institutional Biosafety Committee including deadlines and meeting schedule, [click here](https://ehs.ncsu.edu/home-page-info/biological/ibc/).

**Directions:** Complete Part A for all submissions.For subsequent Part,if a question does not apply or was addressed in a different section, please indicate with an “n/a” or other written designation (*do not leave blank*). Initiation of a proposed amendment involving use of biological materials is dependent upon IBC approval. Work practices alternative to the NC State Laboratory Biosafety Manual must be included as a safety SOP with this form. Submission instructions are located in the PI signature section at the end of the form.

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

**Part A: General Information**

1. **Principal Investigator:**  Telephone: --

Dept. Name: **Email:**

2. **Secondary Contact (*required*):**  Telephone: --

 Title: Email:

3. Current IBC#:

4. **Biosafety Narrative and Risk Assessment for Amendment**

*For each section below, do not cut-and-paste or attach from grant proposals or IACUC forms here. Those forms do not cover the information required for an IBC review.*

4a. Describe in non-scientific terms the goal/purpose of the Amendment. Committee members may not be familiar with your area of expertise. Clarify what is new in comparison to the original submisson.

4b. Characterize the experimental methods to be used in the Amendment. **Briefly list common approaches and techniques** but **expand on less familiar or novel ones**. Provide a clear step-by-step description of how organisms and/or biological materials are processed from the time of receipt to the end of use. Include how material is **originally obtained, transported, logged, stored, etc.**

4c. **Identify the inherent biological hazards (biohazards)** associated with the planned procedures and manipulations. What procedures and manipulations with these biohazards increase the risk of exposure for the specific work being done? Include enough information to allow Committee members to **accurately assess the potential sources of risk to personnel and/or the environment** (e.g., pollen or interbreeding with wild species).

4d. **Discuss how the risks above will be managed in your unique setting**. Explain safety and containment precautions to be used to address new hazards—reference the [NC State Biosafety Manual](https://drive.google.com/open?id=0Bwfv9WVwZC73R3lRclA1RTlPSjQ) as necessary, and reference any included safety SOP’s. *If not listed or referenced, reviewers will assume controls are not in place.*

4e. **Provide a brief description of the facilities** where the new work will take place. Include areas with shared equipment. If BSL-2, what items on the [NC State BSL-2 Checklist](https://drive.google.com/file/d/1K6vwwHFfiR9yxMtueS9TVfARUM2wieId/view?usp=sharing) still need to be addressed?

**Part B: Location Change (review the table above Part A to determine if Part B is necessary)**

1. Use the table below to indicate change in location only. Do not list locations that will remain the same from your previous submission. If the location has never before been associated with the BUA, indicate “NA” in the columns for Previous Location Information.

|  |  |
| --- | --- |
| **Previous Location Information** | **New Location Information** |
| **Campus, Building and Room number of Current Location**  | **Current Containment Type and Level** | **Campus** | **Building** | **Room #** | **Containment Type and Level** |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

1. Are there changes in Personal Protective Equipment (PPE) that are readily available to workers and used while conducting hazardous tasks in this registration?

[ ] No [ ] Yes. If yes, specify changes:

1. Are there changes in safety and containment equipment that are readily available to this project ?

[ ] No [ ] Yes. If yes, specify changes:

1. Are there changes in sharp instrument use and/or management?

**NOTE: If cut or struck by a contaminated sharp object, you must wash the wound immediately and report to urgent care within 2 hours.**

[ ] No [ ] Yes. If yes, specify the materials and additional practices:

1. Are there changes in routine decontamination and/or disinfection procedures?

[ ] No [ ] Yes. If yes, specify changes:

1. Are there changes in cleanup procedures for biological materials in the event of a spill or release (Spill Control Plan)?

[ ] No [ ] Yes. If yes, specify changes:

1. Are there changes in the occupational health surveillance program in place (e.g. animal handler questionnaire, respirator use, titers, vaccines, etc.)?

[ ] No [ ] Yes. If yes, specify changes:

To contact Campus Health for advice or to make an appointment to receive a medical service, see EHS Medical Surveillance website at <https://ehs.ncsu.edu/occupational-health/medical-surveillance/>

1. Other comments (*space expands indefinitely*):

**Part C: Recombinant DNA**

Use this section to register recombinant DNA in organisms (i.e. the joining of naturally occurring or synthetic DNA sequences (insert) to molecules capable of replicating in a host cell (vector) and/or subsequent introduction of those constructs into living cells). Organisms listed in Part C should not be listed in Part D.

1. Refer to the NC State [Classification Guide](https://drive.google.com/file/d/0Bwfv9WVwZC73Y0hmdmFMREhuMFE/view). Under what Sections(s) of the NIH Guidelines is this research classified?

1. Is a deliberate attempt made to obtain expression of foreign gene(s)? [ ]  **YES** [ ]  **NO**

**If YES:** List the following: (1) the recombinant gene inserts to be used; (2) source species (mouse, human, bacterial species, etc.); (3) function of the insert if known; and (4) please mark by an \* all inserts that may pose a specific hazard or risk. Include oncogenes, toxin genes, inhibitors of tumor suppression genes, other genes that encode proteins.

**Example:** *myo-3 / C.elegans / body wall mysoin protein \**

1. Describe in detail the function and potential hazards from the gene inserts marked by \* in Question 2. For inhibitory RNA molecules, discuss consequences of the loss of the targeted gene product and potential off-target effect.

1. List all vector/host systems to be used and source (e.g., bacterial expression plasmid cloned in lab strains of *E.coli*, mammalian expression plasmid transfected into cell culture, replication-deficient adenovirus infecting mouse neurons):

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. List all cells to be used with recombinant nucleic acids, including the source species (note that work with human or primate cell lines requires BSL-2 containment and completion of Part H):

1. Are all **decontamination and disinfection** procedures listed on Part B of this form appropriate for this material? [ ]  **YES** [ ]  **NO**

If *YES* skip to #8. If *NO*,, indicate which decontamination and disinfection procedures differ from Part B (*check all that apply*):

Decontamination and disinfection procedures in use must follow the [NC State Laboratory Biosafety Manual](https://drive.google.com/open?id=0Bwfv9WVwZC73R3lRclA1RTlPSjQ).

[ ]  Work surfaces and equipment are disinfected after working and at the end of each day. Describe procedure including chemical disinfectant, concentration, and contact time:

[ ]  Liquid waste is disinfected prior to sewage disposal. Describe procedure including chemical disinfectant, concentration, volumes, and contact time:

**General Queries**

Does this project involve any of the following? (if ‘yes’ to any of the following questions, describe in the Biosafety Narrative)

1. Genetically modified microorganisms or genetic elements that contain nucleic acid sequences coding for any of the toxins listed on the [CDC List of Select Agents, or their toxin subunits](http://www.selectagents.gov/SelectAgentsandToxinsList.html)? [ ] **YES** [ ] **NO**
2. Genetically modified microorganisms or genetic elements from organisms listed on the [CDC List of Select Agents](http://www.selectagents.gov/SelectAgentsandToxinsList.html) shown to produce or encode for a factor associated with a disease? [ ] **YES** [ ] **NO**
3. Molecular cloning/expression of any toxic genes that encode toxins? [ ] **YES** [ ] **NO**
4. Growth of cultures in volumes of 10 liters or greater at one time? [ ] **YES** [ ] **NO**
5. Release of recombinant organisms into the environment? [ ] **YES** [ ] **NO**
6. Transfer of antibiotic or other drug resistance to a pathogen, if doing so might compromise the use of the drug therapeutically? (Check yes only if this drug is used to treat human or animal infections caused by this organism.) [ ] **YES** [ ] **NO**

**Viral Vectors**

Complete these questions ONLY if you are conducting work with a viral vector.

1. Describe in detail each viral vector to be used. Indicate the wild-type parent virus and describe features of the viral vector, if any, that are intended to reduce the likelihood of a recombination event that would lead to a replication-competent vector (e.g., gene deletions, expression of packaging genes on multiple plasmids, self-inactivating long terminal repeats).

1. Describe the risks that would be associated with accidental human exposure to the viral vector, including the probability and consequences of (1) recombination events leading to restoration of a replication-competent virus, (2) expression of the gene insert product, and (3) integration of the viral vector into the host genome leading to insertional mutagenesis.

1. Please indicate your approach to replication competence for this vector:

[ ]  This vector is capable of replication. Appropriate precautions for safe lab and/or animal work are described in my Biosafety Narrative or attached safety SOP.

[ ]  The vector is intended to be replication deficient. However, the research will be conducted under conditions that would be appropriate for a replication-competent vector (RCV) that could arise as a result of a recombination event. Appropriate precautions for safe lab and/or animal work are described in my Biosafety Narrative or attached safety SOP.

[ ]  The vector is intended to be replication-deficient. Every vector stock will be screened for the presence of RCV prior to use in the lab or injection in animals. I have attached a detailed SOP describing the screening assay, including the target level of detection for RCV in virus stock, the quantity of virus stock to be screened, and the positive control to be used to demonstrate sensitivity of the assay.

**Recombinant DNA in animals or plants**

Complete these questions ONLY if you are working with rDNA in any animals (vertebrates or invertebrates) or plants, or with genetically-modified animals or plants (knockouts, transgenics, etc.).

1. List all species of plants or animals (vertebrate or invertebrate) that will be involved in the rDNA research, including genetically-modified plants or animals: If live arthropods, see Part E. For other live animals, see Part F.

1. Will attempts be made to insert recombinant DNA into the germ line in order to establish a genetically-modified animal or plant (i.e., producing a transgenic animal or plant)?

[ ] **YES** [ ] **NO**

If yes, explain:

1. Will there be an attempt to cross-breed two or more genetically-modified animals or plants?

[ ] **YES** [ ] **NO**

If yes, explain:

1. Do these experiments involve the use of existing genetically-modified animals or plants?

[ ] **YES** [ ] **NO**

If yes, explain:

For plants only:

1. Where will the plants be housed?

1. Describe plant/tissue disposal practices:

**Part D   : Biological Agents / Materials containing biological agents Not Listed Elsewhere**

To be completed for organisms, viruses, and biologically active agents that require registration as defined in the [NC State Laboratory Biosafety Manual](https://drive.google.com/open?id=0Bwfv9WVwZC73R3lRclA1RTlPSjQ) and not listed on another Part of this submission unless otherwise directed by EHS. For [duplicates of this page, click here.](http://safety.ncsu.edu/Bioforms/BUA_Part_D.docx)  Do not duplicate more than 5 times, instead contact the EHS Biosafety Section.

1. Name of Biological Agent:  Strain, Designation :

Source of isolate(s):

1. Associated with disease in: [ ] **Human (Risk Group 2** [ ] , **3**[ ] **)**  [ ] **Animal** [ ] **Plant (*plant pests*)** [ ] **None per lit.**

**review** (skip question #13)

**For agents associated with disease in humans**

1. Adverse effects on humans including signs/syptoms (for resources see pp. 11-12 of the [NC State Laboratory Biosafety Manual](https://drive.google.com/open?id=0Bwfv9WVwZC73R3lRclA1RTlPSjQ)):

1. Modes of Transmission
2. Natural mode(s) of transmission in the absence of mitigating factors: **examples: inhalation, ingestion, inoculation, skin/mucous membrane contamination**
3. Known or suspected routes of transmission of laboratory-associated infections: **examples: inhalation, ingestion, inoculation, skin/mucous membrane contamination**
4. Vaccines or treatments available: **do not leave blank, indicate unknown, N/A as applicable**
5. Is agent listed on the [CDC List of Select Agents](http://www.selectagents.gov/SelectAgentsandToxinsList.html)? [ ]  **YES** [ ]  **NO**
6. Is antibiotic resistance expressed for agents listed in this Part D? [ ]  **YES** [ ]  **NO**

List other markers *(indicate “N/A” if not applicable*)?

1. Are you isolating, purifying, or concentrating toxin from the agent? [ ]  **YES** [ ]  **NO**

 If *YES*, **also complete Part G Biological Toxins**

1. Scale of growth/culture of agent : (C*heck all that apply. If 1 liter or greater, describe in Narrative or in Other Comments below*): [ ]  **Agent is not grown or cultured** [ ]  **Diagnostic scale only (less than 10 Petri dishes or T-25 flask at a time)**

 [ ]  **Up to 1 liter volumes** [ ]  **Between 1 and 10 liters** [ ]  **Greater than 10 liter volume**

1. Are the organisms and/or biological materials concentrated/purified in viable form from cultures? [ ]  **YES** [ ]  **NO**

If yes, describe method(s) of concentration, safety precautions, and location:

1. Will open cultures or other materials be manipulated outside a BSC? [ ]  **YES** [ ]  **NO**

If yes, describe this location here and use the Biosfaety Narrative to describe measures to be used for the protection of

personnel and/or the environment or to reference safety SOPs:

1. Are all **decontamination and disinfection** procedures listed on Part B of this form appropriate for this material? [ ]  **YES** [ ]  **NO**

If *YES* skip to #13. If *NO*,, indicate which decontamination and disinfection procedures differ from Part B (*check all that apply*):

Decontamination and disinfection procedures in use must follow the [NC State Laboratory Biosafety Manual](https://drive.google.com/open?id=0Bwfv9WVwZC73R3lRclA1RTlPSjQ).

[ ]  Work surfaces and equipment are disinfected after working and at the end of each day. Describe procedure including chemical disinfectant, concentration, and contact time:

[ ]  Liquid waste is disinfected prior to sewage disposal. Describe procedure including chemical disinfectant, concentration, volumes, and contact time:

1. If a pathogen of livestock animals, avian species, or for plants (including plant pests) have you obtained a valid APHIS permit?

[ ]  **YES** [ ]  **NO** [ ]  **In progress** [ ]  **Not applicable**

1. Will the organisms and/or biological materials) be used in animals? [ ]  **YES** [ ]  **NO**

*If yes*, complete Part F Live animal use.

1. Will the organisms and/or biological materials be used in plants? [ ]  **YES** [ ]  **NO**

*If yes*, describe method(s) of plant disposal:

1. Will the organisms and/or biological materials be used in arthropods? [ ]  **YES** [ ]  **NO**

*If yes*, complete Part E Arthropods *unless* the species does not pose a public health concern.

1. Other comments (*space expands indefinately*):

**Part E: Arthropods**

To be completed only for projects involving arthropods that pose a public health concern. This section should not be completed for *Drosophila* spp. unless they are modified in such a manner that they would be of public health concern. If the quesiton is not applicable to your research, type in “N/A” or “Not Applicable”.

1. Genus and Species

Phenotype known to be rDNA modified, or insecticide resistant?:

1. Known to be free of specific pathogen(s)? [ ]  Yes [ ]  No

2.a. *If Yes*, which pathogen(s)?:

2.b. *If No*, the following should be considered:

2.b.1 Why would an infectious agent be suspected?

2.b.2 What route of transmission is indicated

2.b.3 Are agents that the arthropod transmits transmitted horizontally?

2.b.4 Are there reasons to believe that a novel or unknown agent is present?

2.b.5 What epidemiologic data are available?

2.b.6 What is the morbidity or mortality rate associated with the agent?

1. Is the arthropod species already established in the locale?

If the arthropod is exotic, explain the likelihood that the arthropod would become temporarily or permanently established in

the event of accidental escape?

1. Are agents that the arthropod could reasonably be expected to transmit present in the locale or has the agent been present in the

past?

1. Would accidental release of the arthropod significantly increase the risk to humans and animals above that already in existence in the

event of introduction of exotic pathogens in the area?

1. In the case of zoonotic diseases, does the animal reservoir exist in the locale, and, if so, what is its infection status?

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

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

If so, it should be handled under the more stringent conditions within Arthropod Containment Level 2 even if uninfected.

1. Are disabled strains available whose viability after escape would be limited (e.g. eyecolor mutants, cold-sensitive)?

1. All life stages of the arthropod are inactivated by (*check all that apply*):

 [ ]  Autoclave. Validation is performed with SteriGage Test Pack according to [Biosafety Manual](https://drive.google.com/open?id=0Bwfv9WVwZC73R3lRclA1RTlPSjQ). **PI initials required**:

 [ ]  An alternative to autoclaving is performed (e.g., freezing, chemical).

 [ ]  The protocol and validation procedure is attached.

 [ ]  The protocol and validation procedure is described here:

1. Will the will the arthropods be used with animals? [ ]  Yes [ ]  No

*If yes*, complete Part F Live animal use.

1. Other comments:

**Part F: Live Animal Use**

To be completed for projects involving live vertebrate animals. Use this form to accurately convey the procedures and hazards to the IBC and animal handlers. This form must be forwarded to animal handlers prior to initiating genetically modified animal work or animal work with biological agents.

**Animal information**

1. Describe the animals used in this study. Include the number of animals, species, and duration.

1. Where will the animals be housed? Provide all information presently available (e.g. CVM LAR Finger Barn 3; CALS BRF room 213; Research Station in Clayton, NC; Univ. Field Lab on Lake Wheeler Road; etc.).

1. How are animals housed? [ ]  Common animal room [ ]  Animal isolation area

[ ]  Other, explain:

1. Has the work been submitted to the IACUC for approval? [ ] YES [ ]  NO
2. Are you registering use of transgenic animals only (no use of biological agents in animals)? [ ] YES [ ]  NO

If YES, skip to question 16.

**Agent information and handling practices**

1. Describe procedures and engineering controls used for animal handling (e.g., biosafety cabinet).

1. List the biological agent(s) administered to animals that may pose a hazard to humans. Include route of administration, frequency, and dosage. If known, also include how long the animal may shed the agent into surroundings.

1. Describe the known or potential adverse effects or hazards to humans.

1. Building and room where agent is used in animals:
2. Indicate the minimum level of personal protective equipment designated for handling exposed animals and their cages/cage contents:

[ ]  Gloves (single layer) [ ]  Double Gloves [ ]  Safety glasses [ ]  Goggles [ ]  Laboratory coat [ ]  Solid front gown

[ ]  Face shield [ ]  Surgical mask

[ ]  Other PPE or special practices (specify):

1. Are all **decontamination and disinfection** procedures listed on Part B of this form appropriate for this material? [ ]  **YES** [ ]  **NO**

If *YES* skip to #11. If *NO*,, indicate which decontamination and disinfection procedures differ from Part B (*check all that apply*):

Decontamination and disinfection procedures in use must follow the [NC State Laboratory Biosafety Manual](https://drive.google.com/open?id=0Bwfv9WVwZC73R3lRclA1RTlPSjQ).

[ ]  Work surfaces and equipment are disinfected after working and at the end of each day. Describe procedure including chemical disinfectant, concentration, and contact time:

[ ]  Liquid waste is disinfected prior to sewage disposal. Describe procedure including chemical disinfectant, concentration, volumes, and contact time:

1. Appropriate Animal Biosafety Level (if more than one is checked, please explain): [ ]  ABSL-1 [ ]  ABSL-2

**Changing and Disposal Practices**

1. Cage Change Instructions (*check all that apply*):

[ ]  changed by PI or laboratory personnel 🡪 *please check one*: [ ] initially [ ]  always;

[ ]  changed by husbandry staff; [ ]  changed in hood; [ ]  change within animal isolation area; [ ]  No special requirements

[ ]  Other, explain:

1. Cage cleaning: [ ]  no special requirements; [ ]  autoclave prior to dumping/cleaning;

[ ]  Other, explain:

1. A) Disposal of feed and bedding will be performed by: [ ]  Animal Facility [ ]  Prinicpal Investigator [ ]  No special requirements

[ ]  Other, explain:

B) Method of feed and bedding disposal: [ ]  Incinerate [ ]  Autoclave [ ]  No special requirements

[ ]  Other, explain:

1. A. Disposal of carcass will be performed by [ ]  Animal Facility; [ ]  Prinicpal Investigator; [ ]  Not disposed (live animals are transferred)

B. Method of animal disposal/transfer (*check all that apply*):

[ ]  No special requirements

[ ]  Disposal per animal isolation area

[ ]  Incineration is required, alternative methods of disposal are not allowed

[ ]  Hold for PI, explain (include final disposition):

[ ]  Live animals are transferred/returned to study provider, explain (include final disposition):

[ ]  Other, explain:

1. Disposal of water and bottle: [ ]  Autoclave [ ]  No special requirements

[ ]  Other, explain:

1. Describe procedures for transporting infectious agents/materials and animals/tissue to and from animal facilities:

1. Comments

1. PI certification: If I use biological agents in animals in any NCSU facility, I will contact an authorized representative of the animal facility before use.

 **PI initials required**:

Upon approval by the IBC, the PI should forward a copy of applicable sections of this document (e.g. Part A, Part C, Part D, Part F, etc.) to animal husbandry staff and discuss any questions they may have.

**Part G: Biological Toxins**

To be completed for work with toxins produced by living organisms on campus or toxins described in the Select Agent Program..

1. Toxin(s):  Subtype(s):
2. LD50:  for [ ]  humans [ ]  rodents [ ]  other vertebrate animal
3. Amount of toxin used in a single experiment:  Maximum inventory of toxin at any time:
4. Is toxin listed on the [Federal List of Select Agents](http://www.selectagents.gov/SelectAgentsandToxinsList.html)? [ ]  Yes (continue below) [ ]  No (skip to question 5)
	1. Will the amount exceed, at any time, the [Select Agent Permissible Toxin Amounts](http://www.selectagents.gov/PermissibleToxinAmounts.html)? [ ]  Yes [ ]  No

PI Comments:

The Federal Select Agent Program developed the ["toxin due diligence" provision](http://www.selectagents.gov/faq-diligence.html) to address the concern that someone might stockpile toxins by receiving multiple orders below the excluded amount. The following are required of the Principal Investigator:

* 1. Indicate how you will use due diligence to assure that a recipient has a legitimate need to handle or use such toxins

(*check all that apply*):

[ ]  I will require the recipient to complete and submit to me documentation stating their intended use of the toxins. Information pertinent to the person requesting and using the toxins includes the individual's name, institution name, address, telephone number, and e-mail address.

[ ]  I will document my knowledge of the recipient's legitimate need for the toxins. Information pertinent to the person requesting and using the toxins includes the individual's name, institution name, address, telephone number, and e-mail address.

* 1. If I detect a known or suspected violation of Federal law or become aware of suspicious activity related to the toxin, I will immediately notify the Biological Safety Officer at 919-515-6858 to contact the Federal Select Agent Program at 800-447-8477. **PI initials required**:
1. Chemical/disinfectant used for inactivation and contact time:
2. Signs/symptoms of human exposure:
3. Are all **decontamination and disinfection** procedures listed on Part B of this form appropriate for this material? [ ]  **YES** [ ]  **NO**

If *YES* skip to #13. If *NO*,, indicate which decontamination and disinfection procedures differ from Part B (*check all that apply*):

Decontamination and disinfection procedures in use must follow the [NC State Laboratory Biosafety Manual](https://drive.google.com/open?id=0Bwfv9WVwZC73R3lRclA1RTlPSjQ).

[ ]  Work surfaces and equipment are disinfected after working and at the end of each day. Describe procedure including chemical disinfectant, concentration, and contact time:

[ ]  Liquid waste is disinfected prior to sewage disposal. Describe procedure including chemical disinfectant, concentration, volumes, and contact time:

1. Will the will the toxin be used with animals? [ ]  Yes [ ]  No

*If yes*, complete Part F Live animal use.

1. PI Comments:

**Part H: Human or Non-Human-Primate Derived Material (includes established human cell lines)**

(to be completed for research using human or non-human primate blood, body fluids, cell lines, or unfixed tissues or Other Potentially Infectious Material as defined by [OSHA Standard 1910.1030](https://ehs.ncsu.edu/home-page-info/biological/bloodborne-pathogens/).). Only list human fecal material in Part D.

1. Identify the samples to be manipulated (*check all that apply*):

 [ ]  Human *only* [ ]  Non-human primate (NHP) *only* [ ]  Human *and* NHP

1. Categorize the material(s) below then describe or list specific information including source (e.g. ATCC and # if known). If Human *and* NHP used, specify which.

[ ]  Whole blood/serum:

[ ]  Established cell lines:

[ ]  Blood component:

[ ]  Unfixed tissues:

[ ]  Primary cells:

[ ]  Tissue from animals infected with HIV or HBV or cell lines/repository cells infected with HIV/HBV:

[ ]  Other

1. Has any donor material listed above been screened for adventitious agents? [ ]  NO [ ]  YES

If YES, Describe which donor material has been screened and for what agents:

**Laboratories working under the OSHA Bloodborne Pathogens (BBP) standard follow the NC State** [**Laboratory BBP Exposure Control Plan**](https://drive.google.com/file/d/1Tgx4EV2SRoTL85aiU4EDV887zK_QFOPb/view?usp=sharing)**. This includes all laboratory work in research, courses, and diagnostics involving human and NHP blood, tissues, body fluids and all cell lines (primary or established). The following three questions apply to this research:**

1. Have all personnel working with this material review the Laboratory Exposure Control Plan? [ ]  Yes [ ]  No
2. Have all personnel working with this material received or declined in writing the [hepatitis B vaccine](https://ehs.ncsu.edu/home-page-info/biological/bloodborne-pathogens/)? [ ]  Yes [ ]  No

*If NO,* list deadline(s) PI has given to workers:

1. Have all personnel working on this project received NC State [bloodborne pathogen training](https://ehs.ncsu.edu/home-page-info/biological/bloodborne-pathogens/) within the past year? [ ]  Yes [ ]  No

*If NO*, provide explanation:

1. Has this project been reviewed by the Institutional Review Board (IRB)? [ ]  N/A [ ]  review in progress [ ]  Yes [ ]  No
2. NOTE: Per OSHA BBP Standard, 70% alcohol may ***not*** be used as a disinfectant. [Review approved EPA disinfectants here](https://www.epa.gov/pesticide-registration/selected-epa-registered-disinfectants).

Are all **decontamination and disinfection** procedures listed on Part B of this form appropriate for this material? [ ]  **YES** [ ]  **NO**

If *YES* skip to #8. If *NO*,, indicate which decontamination and disinfection procedures differ from Part B (*check all that apply*):

Decontamination and disinfection procedures in use must follow the [NC State Laboratory Biosafety Manual](https://drive.google.com/open?id=0Bwfv9WVwZC73R3lRclA1RTlPSjQ).

[ ]  Work surfaces and equipment are disinfected after working and at the end of each day. Describe procedure including chemical disinfectant, concentration, and contact time:

[ ]  Liquid waste is disinfected prior to sewage disposal. Describe procedure including chemical disinfectant, concentration, volumes, and contact time:

1. Will the material(s) be used with animals? [ ]  Yes [ ]  No

*If yes*, complete Part F Live animal use.

1. Comments:

**Statement of Informed Consent**

Principal Investigator Instructions: **1. Prior to submission** of this BUA for IBC review, list all personnel in the table below who may be involved with this project and may be expected to handle materials listed herein. Include the PI, graduate/student workers, lab technicians, visiting scholars, workers autoclaving waste, etc., and provide a job title. Only the PI is required to complete the online Biosafety Training prior to approval. **2.** **After you receive notification of approval**, use the approved BUA to have each member indicate the date they completed Biosafety Training and sign the form. The PI is responsible for updating the list below as new members join the project. Biosafety Training is available upon request to the Biosafety Officer or online at <https://ehs.ncsu.edu/training/> (Required every three years). On the numbered statements below, use the blanks as necessary to adopt the form to meet the needs of the project.

Personnel Instructions: Please complete the Laboratory Biosafety Training as prescribed by your Principal Investigator; the online Laboratory Biosafety Training link is above, the exam is accessed from the very last training slide. Upon successful completion of the Laboratory Biosafety Training exam, workers receive a confirmation email which they should print and maintain per PI instructions. That training date is recorded on this and subsequent forms.

All personnel involved with this project who may be expected to handle materials listed herein, must read and sign below.

1. I am aware that I will participate in activities that involve potential exposure to the biological agents listed in this Biological Use Authorization (BUA) form(s).
2. I have read and understand the materials listed in this Biological Use Authorization and completed NC State’s online Biosafety Training.
3. I have read and understand NC State University’s Laboratory Biosafety Manual including sections for waste disposal, training, emergency procedures (dial 911), and the follow-up requirement to report all spills, releases, or accidents involving materials listed herein--regardless of how minor the event or how remote the location--to the Biological Safety Officer at 919-515-6858.
4. I understand that the materials listed on the BUA form(s) have been reviewed by the Institutional Biosafety Committee and the Department of Environmental Health and Safety and have been approved for use **only** under certain containment conditions.
5. I am aware that inherent risks may be associated with the agents listed in the BUA form(s) and I am advised to discuss with my physician, supervisor, and/or EHS any concerns I have regarding my immune status (illness, medications, pregnancy, etc.).
6. I have been trained in practices, procedures and the use of barriers that, when properly employed in this laboratory, will provide containment suitable for the agents listed in the BUA form(s).

My signature indicates that I am aware of, understand, and agree to abide by the above stated conditions:

|  |  |  |  |
| --- | --- | --- | --- |
| Name(for more names, each box expands indefinately) | Job Title | Biosafety Training Date (Must be less than 3 Years before date of submission) | Signature  |
|       | Principal Investigator |      (required by PI prior to approval) |  |
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**Acknowledgement of Principal Investigator – review the information for each box that applies to this project, course, or diagnostic lab. Check the box only if you agree. Complete all Dual-use Concern questions, then sign as appropriate.**

[ ]  **Part C: Recombinant DNA**. As the Principal Investigator for this protocol, I understand and acknowledge my responsibilities under the NIH Guidelines and the NC State Laboratory Biosafety Manual. I accept responsibility for the safe use of all recombinant organisms at the established Biosafety Level and have informed all personnel of the risks of exposures to the materials.

[ ]  **Part D: Biological agents** not listed elsewhere. I am familiar with and agree to abide by the provisions of the current CDC/NIH “Biosafety in Microbiological and Biomedical Laboratories” as well as the NC State Laboratory Biosafety Manual. I will assure that research personnel are trained in standard microbiological practices and techniques required to ensure safety for this project, emergency response procedures, exposure incident response procedures, and waste management procedures.

[ ]  **Part E: Arthropods**. I accept responsibility for the safe use of arthropods and agree to follow the safety and containment requirements to be established by the IBC.

[ ]  **Part F: Live Animal Use.** I accept responsibility for the safe use of animals and agree to follow the safety and containment requirements to be established by the IBC and/or the animal facility director.

[ ]  **Part G: Biological Toxins.** I will assure that research personnel are trained in chemical safety techniques and standard microbiological practices required to ensure safety for this project, as outlined in Appendix I--Guidelines for Work with Toxins of Biological Origin of the CDC/NIH *Biosafety in Microbiological and Biomedical Laboratories* as well as the NC State Laboratory Biosafety Manual.

[ ]  **Part H: Human or Non-Human-Primate derived material.** I accept responsibility for the safe use of human blood, body fluids, cell lines, or tissues as prescribed in the OSHA Bloodborne Pathogen Standard and agree to follow Biosafety Level 2 practices and procedures while working with these materials. All personnel have received training in the Exposure Control Plan specific to this laboratory or department.

**Dual-use Concern Questions**

I understand that certain types of experiments could raise concerns about the issue of dual use in life sciences (refer to [NIH OBC Dual Use: a dialogue](https://www.nih.gov/news-events/videos/dual-use-research-dialogue) video for more information). Therefore I attest that this research may

1. Enhance the harmful consequences of a biological agent or toxin; **1.** [ ] **YES** [ ]  **NO**
2. Disrupt the immunity or the effectiveness of an immunization without clinical and/or agricultural justification; **2.** [ ] **YES** [ ]  **NO**
3. Confer to a biological agent or toxin, resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitate their ability to evade detection methodologies; **3.** [ ] **YES** [ ]  **NO**
4. Increase the stability, transmissibility, or the ability to disseminate a biological agent or toxin; **4.** [ ] **YES** [ ]  **NO**
5. Alter the host range or tropism of a biological agent or toxin; **5.** [ ] **YES** [ ]  **NO**
6. Enhance the susceptibility of a host population; **6.** [ ] **YES** [ ]  **NO**
7. Generate a novel pathogenic agent or toxin or reconstitute an eradicated or extinct biological agent. **7.** [ ] **YES** [ ]  **NO**

The information contained in this application is accurate and complete. I have attached safety SOPs for any work practices alternative to the NC State Laboratory Biosafety Manual. I understand that incomplete fields, an incomplete Biosafety Narrative, or inaccurate information may result in significant delays in the processing of this registration.

**Submission Instructions -**

The PI emails this completed form in Microsoft Word (\*.doc) format along with any attachments to env-health-ibc@ncsu.edu with the words “IBC submission” in the subject line. DO NOT SUBMIT THIS FORM AS A PDF FILE.

**I understand that submission of this form by email from my NCSU GoogleApps serves as my signature.**

**Approval of IBC Chair**

The Institutional Biosafety Committee has reviewed the proposed project and has approved the use of these research materials using the containment facilities and practices outlined based on the guidelines of the CDC/NIH “Biosafety in Microbiological and Biomedical Laboratories”.

## *Signature- IBC Chair Date*