# Biological Use Authorization (BUA)

# Form 1: Project Registration and Principal Investigator Form BUA #\_\_\_\_\_\_

 *(Office use only)*

|  |
| --- |
| **Section 1.** |
| **1. Project Title:** |
| **2. PI Name:** | Title: |       |
| Department:      | Phone: |       |
| Building:      | Room: |       |
| E-mail address:      | Fax: |       |
| **3. Co-investigator Name:** | Title: |       |
| Department:      | Phone: |       |
| Building:      | Room: |       |
| E-mail address:      | Fax: |       |
| **4. Lab Contact Name:** | Title: |       |
| Department:      | Phone: |       |
| Building:      | Room: |       |
| E-mail address:      | Fax: |       |
| **Section 2.** |
| **Laboratory Personnel (Including PI, Students, etc.)** | **Training Received** |
| **Name:** | **Phone:** | **Biosafety** | **Bloodborne Pathogens** | **Medical Waste** |
|       |       | [ ]  | [ ]  | [ ]  |
|       |       | [ ]  | [ ]  | [ ]  |
|       |       | [ ]  | [ ]  | [ ]  |
|       |       | [ ]  | [ ]  | [ ]  |
| **Section 3.** |
| **Authorized Lab Locations/Room Usage** |
| **Building** | **Room #** | **Shared Room Y/N** | Biosafety Level for each room(BL1, BL2, BL3) | Storage  | Research | Biosafety Cabinet | Autoclave | Medical Waste | Animal  |
|       |       |       |       | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
|       |       |       |       | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
|       |       |       |       | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
|       |       |       |       | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
|       |       |       |       | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
|       |       |       |       | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| Is IACUC or IRB Approval also being sought in association with this BUA? | [ ] IRB [ ] IACUC |

#

# Biological Use Authorization (BUA)

**Form 2A: Recombinant DNA Form**

|  |
| --- |
| **Section 1:** |
| **Please indicate "Yes/No" for each of the statements below** | **Yes** | **No** |
| 1. The DNA/RNA to be cloned: |
|  1A. Represents more than two-thirds of the genome of a RG1 organism. | [ ]  | [ ]  |
|  1B. Encodes a known oncogene. | [ ]  | [ ]  |
|  1C. Encodes a known toxin. | [ ]  | [ ]  |
| 2. The viral vector to be used will generate an infectious virus. | [ ]  | [ ]  |
| 3. This protocol will be submitted to the NIH for human gene transfer approval. | [ ]  | [ ]  |
| **Section 2.** |
| **Host/vector/gene information** | **RG1** | **RG2** | **RG3** |
| 2A. Hosts:       | [ ]  | [ ]  | [ ]  |
| 2B. Vectors:       | [ ]  | [ ]  | [ ]  |
| 2C. Genes to be cloned:       | [ ]  | [ ]  | [ ]  |
| 2D. DNA/RNA source:       | [ ]  | [ ]  | [ ]  |
| **Section 3.** |  |
| **The project will be conducted at Biosafety Level (check appropriate level or levels)** |
| **Biosafety Level** | **Animal Biosafety Level** | **Plant Biosafety Level** |
| BL1 | **[ ]**  | ABL1 | **[ ]**  | PBL1 | **[ ]**  |
| BL2 | **[ ]**  | ABL2 | **[ ]**  | PBL2 | **[ ]**  |
| BL3 | **[ ]**  | ABL3 | **[ ]**  | PBL3 | **[ ]**  |
| **Section 4.** |
| **1. Target recipient of recombinant DNA (indicate species or cell lines used)** |
| Animals:      | Plants:      |
| Tissue/Cell Culture:      | Other:       |
| Gene therapy: (human, animal, DNA, vaccine, etc.)      |
| **2. Will a deliberate attempt be made to express the gene encoded in the rDNA? If yes, what gene product will be produced?** |

# Biological Use Authorization (BUA)

# Form 2B: Recombinant DNA Form

Check the appropriate registration section(s) requested. Go to: [NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf) for more information.

**III-A.** **Experiments That Require Institutional Biosafety Committee Approval, RAC Review, and NIH Director Approval before Initiation.**

[ ]  Deliberate transfer of drug resistance traits to microorganisms that are unknown to acquire the trait naturally, if such acquisition could compromise use of the drug to control disease agents in humans, veterinary medicine or agriculture.

**III-B.** **Experiments That Require NIH/ORDA and Institutional Biosafety Committee Approval before Initiation.**

[ ]  Experiments Involving the Cloning of Toxin Molecules with LD50 or Less than 100 Nanograms Per Kilogram Body Weight.

**III-C.** **Experiments That Require Institutional Biosafety Committee and Institutional Review Board Approvals and NIH/ORDA Registration before Initiation.**

[ ]  Experiments Involving the Deliberate Transfer of Recombinant DNA or DNA or RNA Derived from Recombinant DNA into One or More Human Subjects (Please submit completed Appendix M- I, Submission Requirements - Human Gene Transfer Experiments of the NIH Guidelines, along with this document.)

**III-D.** **Experiments That Require Institutional Biosafety Committee Approval before Initiation.**

[ ]  1. Experiments Using Risk Group 2, Risk Group 3, Risk Group 4 or Restricted Agents as Host- Vector Systems.

[ ]  2. Experiments in which DNA from Risk Group 2, Risk Group 3, Risk Group 4 or Restricted Agents is Cloned into Nonpathogenic Prokaryotic or Lower Eukaryotic Host-Vector Systems.

[ ]  3. Experiments Involving the Use of Infectious DNA or RNA Viruses or Defective DNA or RNA Viruses in the Presence of Helper Viruses in Tissue Culture Systems.

[ ]  4. Experiments Involving Whole Animals

[ ]  5. Experiments Involving Whole Plants

[ ]  6. Experiments Involving More than 10 Liters of Culture.

**III-E.** **Experiments That Require Institutional Biosafety Committee Notice Simultaneous with Initiation.**

[ ]  Experiments Involving the Formation of Recombinant DNA Molecules Containing No More Than Two-Thirds of the Genome of Any Eukaryotic Virus.

[ ]  Experiments Involving Whole Plants

**III-F.** **Exempt Experiments**

[ ]  Experiments that are Exempt from the NIH Guidelines.

# Biological Use Authorization (BUA)

**Form 3A: Infectious Agents and Toxins**

|  |
| --- |
| **Section 1.** |
| **Please indicate "Yes/No" for each of the statements below.** | Yes | No |
| 1. I am working with a known or suspected animal pathogen. | [ ]  | [ ]  |
| 2. I am working with a Risk Group 1 organism and producing more than 10 liters of culture. | [ ]  | [ ]  |
| 3. I am working with a Risk Group 2 or Risk Group 3 organism (including replication-defective agents). | [ ]  | [ ]  |
| 4. I am obtaining, receiving, or handling, for research purposes, any of the following human or non-human primate |
| 4A. Tissue, including scrapings, secretions, body fluids, bones or teeth. | [ ]  | [ ]  |
| 4B. Organ culture or primary cell line. | [ ]  | [ ]  |
| 4C. Established cell line. | [ ]  | [ ]  |
| 4D. Blood or blood products such as serum, plasma or cell preparations | [ ]  | [ ]  |
| 5. I am working with toxins known to affect humans and/or animals. | [ ]  | [ ]  |
| **Section 2.** |
| **If you answered "Yes" to any of the above statements, please list below and indicate their source and Risk Group/Biosafety Level**. (Note: If you will be drawing, processing, using, working with or storing: human/non-human primate blood or blood products; unfixed tissues; body fluids; organ or cell cultures, write the name(s) of the potential bloodborne pathogens, and enter "2" for the Biosafety Level.) |
| **Agent/toxin** | **Source** | **BL1** | **BL2** | **BL3** |
|       |       | [ ]  | [ ]  | [ ]  |
|       |       | [ ]  | [ ]  | [ ]  |
|       |       | [ ]  | [ ]  | [ ]  |
|       |       | [ ]  | [ ]  | [ ]  |
| **CDC Select Agents: Please indicate "Yes/No" for the statement below.** | **Yes** | **No** |
| I will be using, storing, shipping or receiving one or more of the CDC designated “Select Agent or Toxin.” A list of the CDC Select Agents/Toxins is included in Appendix C of the Auburn University Biological Safety Manual. If you indicate "Yes,” you must complete the form included in Appendix C and submit it with this application. | [ ]  | [ ]  |

# Biological Use Authorization (BUA)

**Form 4: Project Summary**

|  |
| --- |
|  |
| **Summary:** In each section, please describe your research in a way that will be understood by someone in another field. *Refer to the BUA Form 4 Appendix below to fill out this section* |
| 1. Project Goal(s)/Purpose:      |
| 2. Experimental Procedures:      |
| 3. Containment to be used (including BSC):      |
| 4. Protective Equipment to be used (including Lab Coats, Glasses, Goggles, Glove Types):      |
| 5. Transportation Methods (if applicable):      |
| 6. Decontamination Methods:       |
| 7. Waste Disposal:      |
| 8. Spill/Emergency Procedures:      |

# Biological Use Authorization (BUA)

**Form 5: Agents Requiring Health Surveillance and/or Immunization Programs**

If you are working with any of the agents listed below, you must consult with RMS at (344) 844-4870 on the development of an appropriate health surveillance and/or immunization program.

|  |
| --- |
| **Section 1:** |
| **Agent/Program** | **Details** | **Yes** | **No** |
| Bloodborne Pathogen (BBP) | HBV vaccination/declination and post-exposure follow-up and treatment at no cost to the employee, vaccination record retention by the PI, universal precautions, initial BBP training and annual retraining  | [ ]  | [ ]  |
| Q-Fever | Annual medical exams, serologic testing, vaccine use when available, respiratory protection, training | [ ]  | [ ]  |
| Orthopoxviruses (vaccinia and others) | Medical screening, vaccination and contraindication awareness, training | [ ]  | [ ]  |
| Prion Research | Training and special procedures for exposure reporting, decontamination and records handling | [ ]  | [ ]  |
| Cercopithecine Herpesvirus-1 (Herpesvirus simiae) | Post-exposure follow-up and treatment at no cost to employee, training | [ ]  | [ ]  |
| Health History Form | Completed | [ ]  | [ ]  |
| **Section 2:** |
| **Please provide a one paragraph description of your health surveillance and/or immunization program. Has RMS been consulted?**  |
|       |

# Biological Use Authorization (BUA)

**Form 6: PI Certification**

**Principal Investigator's Certification:**

By signing below, I certify that I have read the following statements and agree that I and all participants will abide by these statements and all Auburn University policies and procedures governing the use of recombinant DNA, infectious agents, and other biological materials, as outlined in this application and in the Auburn University Biological Safety Manual.

**I will:**

1. Ensure that listed personnel have received or will receive appropriate training in safe laboratory practices and the procedures for this protocol before any work begins on this project and at least annually thereafter. In addition, all listed personnel who have occupational exposure to bloodborne pathogens will attend annual bloodborne pathogen training sessions conducted by RMS.
2. Follow the health surveillance practices as approved for this protocol and inform those working on the protocol about appropriate emergency assistance information for their location(s).
3. Inform RMS of any research-related accident or illness as soon as possible after its occurrence.
4. Submit in writing a request for approval from the IBC of any significant modifications to the study, facilities or procedures. Contact RMS for information.
5. Adhere to the Auburn University biosafety guidelines referred to in this application.
6. Ensure that all animal use will follow Auburn University Institutional Animal Care and Use Committee policy.
7. Ensure that all biohazardous waste or sharps waste will be handled in accordance with RMS medical waste guidelines.
8. Ensure all use of recombinant DNA/RNA, infectious agents or toxins, humans, or non-human primates or their tissues or cell lines will be performed in accordance with Auburn University Institutional Review Board for Use of Human Subjects in Research policy.

|  |  |
| --- | --- |
| **Signature, PI:** | Date: |
| **Signature, Department Chairperson:** | Date: |
| **Signature, Shared Space PI:** | Date: |

***For IBC Use Only***

|  |  |
| --- | --- |
| [ ]  **IBC Approval****Signature, IBC Chairperson:** | Date: |
| **BSO Review Initials:** | Date: |

**\*\*Submit completed forms with all signatures electronically to** **Biosafety@auburn.edu**

***BUA Form 4 Appendix***

|  |  |  |
| --- | --- | --- |
| **SECTION #** | **RESEARCH ACTIVITY or MATERIALS** | **POINTS TO CONSIDER WHEN WRITING THE BUA PROTOCOL** |
| 1: Project Goal(s)/Purpose | Summary of objectives/aims | * The objective/scope of the research so that a non-scientist can understand.
* The rationale for the use of agent(s) (e.g., In this section of the application writing something such as: For rDNA - *“A” cells will be transfected with “X” gene using viral delivery methods in order to overexpress “X” gene and examine how this affects cellular health markers.*
 |
| 2: Experimental Procedures | Summary of experimental procedures | The Biosafety Committee assesses the risks based on steps that involve the greatest likelihood of exposure to the researcher or environment.Provide sufficient and detailed information on experimental procedures to be conducted that can be understood by a non-scientist. Avoid using highly technical terminology. Please define all abbreviations and acronyms.* Address not only what you will do, but how you will do it. Standard procedures can be referred to by common name (e.g., Southern blot, PCR, transfection by electroporation) but novel procedures and significant modifications to standard procedures should be described. This level of detail is very important to the IBC.
 |
|  | Infectious/biohazardous agents | * Include the method of culture (e.g., agar plates or liquid), size of culture (e.g., anticipated # of 100 mm plates and accompanying media), method of liquid culture (e.g., aerated, or static), and location of culture (e.g., benchtop or incubator).
* Describe methods and materials used for both growing and recovering cells or tissue.
* When describing what will be done after cells are harvested attach the manufacturer's protocols as an appendix. Exceptions can be made for standard techniques such as cell sorting, Western blotting, PCR, or assays where cells or materials will be sent to a commercial vendor.
* List any anticipated hazards that the committee should be aware of if relevant.
 |
|  | Recombinant/synthetic nucleic acids | Describe if experiments will result in new cellular phenotypic characteristics such as enhanced virulence, infectivity, drug resistance, or change in host range.* List the DNA/RNA source (e.g., investigator donation or vendor), list the genes to be cloned, and/or the type and nature of insert.
* Identify general forms of cloning/expression/transfection vectors used (e.g., bacterial plasmids, phage), recipient bacterial strains (e.g., Escherichia coli K-12), and recipient host (e.g., human or animal cell lines, mouse, plant, etc.)
* Indicate the method of gene transfer (e.g., AAV, lentiviral, transfection media, or electroporation)
* Indicate if any gene editing technologies will be used (e.g., CRISPR etc.,)
* As stated above, list any additional anticipated hazards to that the committee should be aware of if relevant.
 |
|  | Viral vectors | * Describe relevant vector information such as the expression plasmid, packaging system used, etc.
* Provide vector maps as an appendix if possible.
* If commercially available, provide the vendor and catalog # or hyperlinks
* Contact the Auburn University Biosafety Officer at biosafety@auburn.edu for university specific guidelines to be used for AAV and lentiviral vectors.
* As stated above, list any additional anticipated hazards to that the committee should be aware of if relevant.
 |
|  | Animals or Plants | * Describe the method of administration and dosage if any of the biohazardous materials including recombinant/synthetic nucleic acid agents are used.
* Describe the safe handling of the agents during administration.
* If the DNA source is from a regulated plant or animal (e.g., USDA) and the regulated organism is grown or stored on-site, indicate the regulatory agency monitoring its use and please include a copy of the regulatory permit
 |
|  | Arthropods (with or without the use of infectious agents) | Describe relevant ACL-1 or ACL-2 containment procedures listed in the following link <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6396570/pdf/vbz.2018.2431.pdf>. |
| 3: Containment | Aerosol generation | * Describe the route of exposure specific to the agent used and provide containment accordingly.
* Describe where these manipulations will take place (e.g., in a biosafety cabinet versus open benchtop, and how aerosols will be contained.
* Describe how aerosols will be minimized with procedures including centrifuging, tissue/cell blending, shaking, sonicating, etc. (e.g., “A centrifuge will be used to separate serum from whole blood with the sealed rotor or by using safety cups).
 |
|  | Usage of sharps | * Describe how inoculation of infectious agents will occur in cells, animals, plants or arthropods.
 |
| 4: Protective Equipment | PPE description | * Describe PPE usage for each proposed research activity/location according to the hazards and risk involved. It should be separate for any animal or plant location.
 |
| 5: Transportation Methods | Safety/compliance provisions for transportation | * Materials should be transported in a sealed leak-proof container which is in a rigid leak-proof secondary (outer) container identified with the appropriate biohazard labeling.
* Transport and shipments of materials outside campus must follow US Department of Transportation (DOT) and International Air Transport Association (IATA) regulations. Contact Tom Hodges (hodgetf@auburn.edu) or Catherine Situma (cns0013@auburn.edu) for assistance.
 |
| 6: Decontamination Methods | Specific methods/procedures for decontamination | * Describe disinfectant agents and contact time used for various phases of the project. Refer to the MSDS for cleaning procedures and EPA for registered disinfectants <https://www.epa.gov/pesticide-registration/selected-epa-registered-disinfectants>
* Describe decontamination used for all consumables, non-consumables, surfaces where work is conducted.
 |
| 7: Waste Disposal | Specific methods/procedures for waste disposal | * Describe that solid biohazardous waste will be collected in leak-proof containers that are lined with a clear/blue autoclave bag, labeled with the biohazard symbol, and closed when not in use.
* Liquid tissue culture waste may be aspirated into a collection flask/container containing bleach, which can then be disposed of in a laboratory sink with excess faucet water.
* Mixed wastes may require special containers, labeling, storage, etc. Contact Risk Management and Safety (RMS - Tom Hodges (hodgetf@auburn.edu)) prior to initiation of any research that might generate mixed waste.
* If waste is being disposed of in the regular trash following the autoclave, include autoclave parameters used for the waste cycle including temperature, time, and pressure. (Recommended – 121C at 15psi for min 30mins)
* All sharps must be placed in an approved sharps container. Sharps that have been exposed to agents that cause human diseases must be autoclaved prior to pick-up by RMS.
* Specify if another method of waste disposal is used in your lab.
 |
| 8: Spill/Emergency Procedures | Procedures to follow for spills and emergencies  | * Indicate how spills will be promptly disinfected and cleaned and indicate the appropriate disinfectants that will be used according to the agents used in research.
* Modify the steps according to the lab/agents used.
* Refer to pages 28 and 29 of the AU Biosafety Manual for specific Biohazard Spill Clean-Up Procedures.

<https://cws.auburn.edu/shared/files?id=227&filename=bsm2.pdf>* For large spills that can cause immediate harm to the laboratory personnel or others indicate that 911 will be called for assistance and RMS will be called thereafter for reporting.
* Refer to AU Exposure Control Plan for post-exposure measures involving any human-sourced materials. <https://cws.auburn.edu/shared/content/files/1382/exposurecontrolplan.pdf>
 |
| Form 5  | Agents requiring health surveillance and/or Immunization Programs | * For Bloodborne Pathogens (blood, urine, and all human-sourced materials including established and primary cell lines)- The hepatitis B vaccination and the declination waiver forms are available as part of the Exposure Control plan –

<https://cws.auburn.edu/shared/content/files/1380/hepb-vaccine.pdf> The forms must be signed and submitted to biosafety@auburn.edu for record-keeping in BioRAFT.* Those who would like to get vaccinated should contact Donna Tucker dwt0007@auburn.edu at RMS
* Any other agents which require medical surveillance are also managed in BioRAFT.
 |