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The University of Texas at El Paso

**Institutional Biosafety Committee**

**New – Triennial Protocol Form**

*Instructions:* Forms need to be completed and submitted via [IRBNet](http://www.irbnet.org/) on the 1st of every month. Submissions entered after the deadline will be considered for review at the following meeting. Meeting dates are posted on the [IBC website](http://research.utep.edu/Default.aspx?tabid=58993). Any questions contact the IBC office at [ibc@utep.edu](mailto:ibc@utep.edu).

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| 1. **PROJECT INFORMATION** | | | | | | | | |
| **SUBMISSION TYPE** | | | | | | | | |
|  | **Initial or Triennial Submission** | |  | **Modification/Amendment**  Make any changes in ***red italicized font*** within the most updated protocol | | | | |
| **ADMINISTRATIVE DATA** | | | | | | | | |
| Principal Investigator | |  | | | | Lab/Office Phone: | |  |
| Lab Room Number: | |  |
| Department: | |  | | | | Emergency Phone: | |  |
| Back-up Emergency # | |  |
| Email Address: | |  | | | | | | |
| Project Title: | |  | | | | | | |
| Funding Source: | | NSF  NIH/PHS  Other (include account #): | | | | | | |
| Grant Title: | |  | | | | | | |
| Grant Proposal Number: | |  | | | | | | |
| IACUC Protocol #:  **If applicable** | |  | | | IRB Protocol number:  **If applicable** | |  | |

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| 1. **PROJECT INFORMATION:** |

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| **1.1a Closing Summary** (If the project is being renewed (*de novo*), please include a summary of the project for the last three years. Describe in non-technical lay terms the purpose of the project).Also include a list of strains for all new infectious organisms generated as a supporting document: |
| **1.1b Summary** (Describe in non-technical lay terms the purpose of the project for the next three years): |

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| **1.2a What do you believe is the required Biosafety Containment Level (e.g., BSL1, BSL2, BSL3)?** | | |
| **1.2b Do you plan to remove material from the BSL3 lab? If Yes, please specify in Section G below on procedures of how and what the inactivation method will be.** | | |
| **1.3 List and describe the organisms to be used in your project on the table. Include information for bacteria, parasites, viruses, cell lines, animals and toxins (if applicable). Include specific name, strain, sub-species or serotype as necessary:**   |  |  |  | | --- | --- | --- | | **Check all that apply:** | **MATERIALS USED:** | **List/Describe:** | |  | Genetically modified animal, plant, or insect |  | |  | Parasites or insects |  | |  | Whole Plant |  | |  | Bacteria |  | |  | Fungi |  | |  | Viruses |  | |  | Recombinant or Synthetic Nucleic Acid Molecules |  | |  | Human or NHP blood, bloodborne pathogens, bodily fluids, blood products, tissue, or cells (including cell cultures), list. |  | |  | Environmental samples (e.g., soil, water, sewer, air), list type and source |  | |  | Select Agents: |  | |  | Other: |  | | | |
| **1.4 Do you intend to ship infectious substances or hazardous chemicals?**  If YES, please, contact Environmental Health and Safety (EH&S x7124) to make arrangements. | YES |  |
| NO |  |
| **1.5 Would this research project demonstrate how to render a vaccine ineffective or confer resistance to therapeutically useful antibiotics/antiviral agents?** | YES |  |
| NO |  |
| **1.6 Would this project potentially increase transmissibility of a pathogen or potentially enable the evasion of diagnostic/detection modalities of an agent?** | YES |  |
| NO |  |
| **1.7 Would this project alter the host range of a pathogen or potentially enable the weaponization of a biological agent or toxin?** | YES |  |
| NO |  |
| **1.8 Will an MTA be needed?** | YES |  |
| NO |  |

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| 1. **WILL YOUR PROJECT INVOLVE:** |

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|  | Creation of transgenic animals, organisms, recombinant or synthetic DNA **(complete Section II below)** |
|  | Use or creation of viral vectors **(complete and include** [**APPENDIX A**](https://www.utep.edu/orsp/institutional-biosafety/forms/index.html)**)** |
|  | Risk Group 2 Organisms **(complete and include** [**APPENDIX B**](https://www.utep.edu/orsp/institutional-biosafety/forms/index.html)**)** |
|  | Risk Group 3 Organisms **(complete and include** [**APPENDIX C**](https://www.utep.edu/orsp/institutional-biosafety/forms/index.html)**)** |
|  | CRISPR- Genome Editing Technologies **(complete and include** [**APPENDIX D**](https://www.utep.edu/orsp/institutional-biosafety/forms/index.html)**)** |
|  | Arthropods  **(complete** [**APPENDIX F**](https://www.utep.edu/orsp/institutional-biosafety/forms/index.html)**)** |

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| 1. **LAB SAFETY, DECONTAMINATION AND DISPOSAL:** |

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| **Check the disinfectants used for surface decontamination and spills:** | | | | | |
|  | **Cavicide** |  | **Bleach** |  | **Other:** |
|  | **Vesphene** |  | **70% Alcohol** |

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| **Check the protective clothing or equipment used when handling this agent(s):** | | | | | | | |
|  | Gloves |  | Double Gloves |  | Lab Coat | | |
|  | Booties |  | Double booties |  | Closed front gown | | |
|  | Surgical mask |  | Safety Glasses |  | Goggles | | |
|  | PAPR |  | Hair cover |  | Centrifuge | safety cups |  |
| sealed rotors |  |
|  | N95 respirator |  | Grinder |  | Splash shields | | |
|  | Sharps containers |  | Blunt ended forceps/scissors |  | Face shied | | |
|  | Ear plugs |  | Capillary tubes |  | Safety needles/scalpel | | |
|  | Sonicator |  | Cell sorter |  | Other: | | |
|  | Chemical Fume Hood, Rm. Location: |  | Biological Safety Cabinet, Rm location: |  | Comments: | | |

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| **Check the method of biohazardous waste disposal:** | |
|  | Placed in **single** red biohazard bag and autoclaved |
|  | Placed in **double** red biohazard bag and autoclaved |
|  | Chemical disinfection then placed in red biohazard bag |
|  | Chemical disinfection of bulk liquid then poured down sanitary sewer |
|  | Autoclaved and placed in bag for incineration |

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| 1. **Study Personnel** |
| **Personnel listed on the project:**  *Please list the names of the individuals who are covered under this protocol. Include their full name, check off their role in the study, and include their UTEP e-mail address.* |

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| **Project Team Members – Identify each current person involved in the design, conduct, or reporting of the research** | | | | | | | | | |
| **Name:**  *First and Last Name* | **E-Mail:**  *Mostly used* | **Team members role on the Project:**  1. Principal Investigator 2. Co-investigator  3. Student 4. Faculty  5. Staff 6. Outside Collaborator  **Check all that apply** | | | | | | | |
| **1** | **2** | **3** | **4** | **5** | **6** | **Experience:** | |
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| **IMPORTANT:** If project personnel is greater than 10 individuals, please add additional rows. | | | | | | | | | |
| **1.8 Has your staff read the entire protocol?** | | | | | | | | YES |  |
| NO |  |
| **1.9 Have you educated your staff regarding safe handling and decontamination procedures for all of the agents or materials listed in the protocol?** | | | | | | | | YES |  |
| NO |  |

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| **Personnel removed from the project (if applicable):**  *Please list the names of the individuals who are no longer involved in this protocol and needs to be removed. Include their full name, email, and reason of removal.* |

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| **Project Team Members – Identify each current person involved in the design, conduct, or reporting of the research** | | |
| **Name:**  *First and Last Name* | **E-Mail:**  *Mostly used* | **Reason of removal:**  *(ex. Left the lab, graduated, etc.)* |
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| 1. **SECTION II: RECOMBINANT OR SYNTHETIC DNA** |

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| **2.1a Will your project involve the use and/or manipulation of recombinant DNA? (**Please indicate the use within the aims below in section G) | YES |  |
| NO |  |
| **2.1b If yes, will this be conducted *in* *vivo/in vitro* with animals?** | YES |  |
| NO |  |
| **2.2 Will your project involve the creation of recombinant DNA and/or synthetic DNA?** | **YES**-  Complete the reminder of the form |  |
| **NO**- proceed to **Section G** |  |
| **2.3 Where will the recombinant or synthetic DNA experiments be performed?** (List all locations applicable and specify building and room number): | | |

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| **2.4 Does your project include the deliberate transfer of a drug resistance trait to pathogenic microorganisms that are not known to acquire the trait naturally?** (Section III-A-1-a, experiments falling under this section of the NIH Guidelines require IBC approval, Recombinant DNA Advisory (RAC) Committee review and NIH Director Approval before initiation; For example the introduction of the gene encoding chloramphenicol resistance into the pathogen Rickettsia conorii)? | YES |  |
| NO |  |
| **2.5 Does your project include cloning toxin molecules with a lethal dose (LD50) of less than 100 nanograms per kilogram body weight?** (Section III-B-1, experiments falling under this section of the NIH Guidelines require IBC approval, and submission to the NIH Office of Biotechnology Activities [OBA] before initiation; For example the cloning of the gene coding for the botulinum toxin.)? | YES |  |
| NO |  |
| **2.6 Does your project include experiments involving the deliberate transfer of recombinant DNA, or DNA or RNA derived from recombinant DNA, into one or more human research participants?** (Section III-C-1, experiments falling under this section of the NIH Guidelines require IBC approval, Recombinant DNA Advisory (RAC) Committee review and IRB approval before initiation)? | YES |  |
| NO |  |
| **2.7 Does your project include experiments using Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents as host-vector systems** (Section III-D-1) that would require BSL-2 or BSL-3 containment (experiments falling under this section of the NIH Guidelines require IBC approval before initiation )? | YES |  |
| NO |  |
| **2.8 Does your project include 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** (Section III-D-2, experiments falling under this section of the NIH Guidelines require IBC approval)? | YES |  |
| NO |  |
| **2.9 Does your project include 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** (Section III-D-3, experiments falling under this section of the NIH Guidelines require IBC approval)? | YES |  |
| NO |  |
| **2.10 Does your project include experiments involving whole animals in which the animal’s genome has been altered by the introduction of DNA into the germ line or experiments involving rDNA modified microorganisms tested on whole animals** (Section III-D-4, III-E-3 – If only Section III-E-3 is applicable then these experiments may be initiated at the same time as IBC registration is in process)? | YES |  |
| NO |  |
| **2.11 Does your project include experiments involving whole plants** (Section III-D-5, III-E-2, If only Section III-E-2 is applicable then these experiments may be initiated at the same time as IBC registration is in process)? | YES |  |
| NO |  |
| **2.12 Does your project include experiments involving more than 10 liters of culture** (Section III-D-6)? | YES |  |
| NO |  |
| **2.13 Does your project include experiments involving the formation of recombinant DNA molecules containing two-thirds or more of the genome of any eukaryotic virus** (Section III-E-1, If only Section III-E-1 is applicable then these experiments may be initiated at the same time as IBC registration is in process)? | YES |  |
| NO |  |
| **2.14 Does your project include cloning into an E. coli K-12 strain or K-12 derivative** (If Yes, this work falls under Section III-F-6 and Appendix C-II)? | YES |  |
| NO |  |
| **2.15 What is the source of rDNA, DNA, RNA to be inserted or cloned?** (Include species of organism from which it is derived): | | |
| **2.16 What is the nature of rDNA, DNA, RNA to be inserted or cloned?** (For example is it a structural gene or oncogene?): | | |
| **2.17 What is the host system to be used**? (For example, Rat cardiomyocytes and HEK-293 cells; or E. coli strain BL21; or yeast): | | |
| **2.18 What is the vector(s) to be used? Include information such as product literature, or vector map describing construction of vector.**  (For example, Lentiviral vector, Invitrogen ViraPower TM): | | |
| **2.19 List any helper virus or packaging cells used?**  (For example 293FT cell line): | | |

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| 1. **EXPERIMENTAL AIMS:** |

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| **Experimental Aim #1** (describe the experimental goal and the specific experiment(s) that will be carried out to accomplish the goal): |
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| **Experimental Aim #2** (describe the experimental goal and the specific experiment(s) that will be carried out to accomplish the goal): |
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| **Experimental Aim #3** (describe the experimental goal and the specific experiment(s) that will be carried out to accomplish the goal): |
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| **Principal Investigator Assurances-Conflict of Interest and Fiscal Responsibility** | | |
| Do you or any person responsible for the design, conduct, or reporting of this study have an economic interest in, or act as an officer or director of any outside entity whose financial interests may reasonably appear to be affected by this research?  If yes, please explain any potential conflict of interest | YES |  |
| NO |  |
| Do you or any person responsible for this study have existing financial holdings or relationships with the sponsor of this study?  If yes, please explain any potential conflict of interest | YES |  |
| NO |  |
| N/A |  |
| **Principal Investigator Certifications:** | | |
| **With this submission I certify that:**  The information provided or attached is accurate and complete  I am familiar with and agree to abide by provisions of the current NIH guidelines for Research Involving Recombinant DNA Molecules and accept the responsibilities listed in Section IV-B-7  I accept responsibility for making sure all laboratory personnel involved in the project has been appropriately trained.  I will ensure that all research personnel are familiar with and understand the potential hazards and relevant biosafety practices, techniques, and emergency procedures associated with this research protocol as dictated by the CDC and NIH document, Biosafety in Microbiological and Biomedical Laboratories (BMBL), 5th Edition (<http://www.cdc.gov/biosafety/publications/bmbl5/index.htm>  I further certify that I will immediately report any injuries or spills that occur while conducting research covered by this IBC protocol to the UTEP Biosafety Officer (747-7179) and the IBC Chair (747-5844) or IBC Coordinator (747-7913) | | |

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| **ADMINISTRATIVE USE ONLY**  **NIH GUIDELINES CLASSIFICATIONS:**  *Please select all categories that apply. See Risk Group (RG) definitions. Full text of the NIH Guidelines can be found at* <http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines> | | | |
| **Risk Group Definitions**  **Risk Group 1 (RG1): Agents that are not associated with disease in healthy adult humans.**  **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 that are associated with serious or lethal human disease for which preventative or**  **therapeutic interventions may not be available.**  **Risk Group 4 (RG4): Agents are likely to cause serious or lethal human disease for which preventative or therapeutic**  **interventions are not usually available.** | | | |
|  | **Section III-E:** Experiments not included in Sections III-A, III-B, III-C, III-D, III-F; and experiments in which all components are derived from non-pathogenic prokaryotes and non-pathogenic lower eukaryotes and may be conducted at BSL1. | | |
|  | **Section III-E-1:** Recombinant or synthetic nucleic acid molecules containing no more than two-thirds of the genome of any eukaryotic virus may be propagated and maintained in cells in tissue culture (BSL1). For such experiments, it must be demonstrated that the cells lack helper virus for the specific families of defective viruses being used. | | |
|  | **Section III-E-2:** Experiments involving nucleic acid molecule-modified whole plants, and/or experiments involving recombinant or synthetic nucleic acid molecule-modified organisms associated with whole plants. | | |
|  | **Section III-E-3:** Experiments involving the generation of rodents in which the animal's genome has been altered by stable introduction of recombinant or synthetic nucleic acid molecules, or nucleic acids derived therefrom, into the germ-line (transgenic rodents). BSL1 containment only; experiments BSL2 or higher are covered under Section III-D-4 | | |
|  | **Section III-D-1:** Experiments Using Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents as Host-Vector Systems. | **RG2:** |  |
| **RG3:** |  |
| **RG4:** |  |
|  | **Section III-D-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. | **RG2:** |  |
| **RG3:** |  |
|  | **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. | **RG2:** |  |
| **RG3:** |  |
|  | **Section III-D-4:** Recombinant or synthetic nucleic acid experiments involving whole animals (e.g., non-human vertebrate or invertebrate organism, including arthropods). | **RG1: (Section II-D-4-a)** |  |
| **RG2 or RG3:**  **(Section II-D-4-a)** |  |
|  | **Section III-D-5:** Experiments involving whole plants or insects. Experiments to genetically engineer plants by recombinant or synthetic nucleic acid molecule methods, to propagate such plants, or to use plants together with microorganisms or insects containing recombinant or synthetic nucleic acid molecules (BSL2 or higher). | | |
|  | **Section III-D-6:** Experiments involving more than 10 liters of culture. | | |
|  | **Section III-D-7:** Experiments involving influenza viruses. | | |
|  | **Section III-F:** Exempt Experiments | | |