**SECTION I: OVERVIEW**

**Principal Investigator:** **Dept.:**

**Project Title:**

**Date:** **Funding Agency:**

**Summary** (describe in non-technical lay terms the purpose of the project):

**Experimental Aim #1** (describe the experimental goal and the specific experiment(s) that will be carried out to accomplish the goal):

**Experimental Aim #2** (describe the experimental goal and the specific experiment(s) that will be carried out to accomplish the goal):

**Experimental Aim #3** (describe the experimental goal and the specific experiment(s) that will be carried out to accomplish the goal):

**List and describe the organisms to be used in your project. Include bacteria, parasites, viruses, cell lines, animals and toxins. Include specific name, strain, sub-species or serotype as necessary:**

**List the 24 hour emergency contact phone number and back-up number for the PI that will be used in the event of an emergency.**

**Do you intend to ship infectious substances or hazardous chemicals? [ ]  Yes [ ]  No.**

If YES, please, contact Environmental Health and Safety (EH&S x7124) to make arrangements.

**Would this research project demonstrate how to render a vaccine ineffective or confer resistance to therapeutically useful antibiotics/antiviral agents? Would this project potentially increase transmissibility of a pathogen or potentially enable the evasion of diagnostic/detection modalities of an agent? Would this project alter the host range of a pathogen or potentially enable the weaponization of a biological agent or toxin?**

 **[ ]  Yes [ ]  No.**

**Will your project involve?**

\_\_\_ **Creation of transgenic animals, organisms, recombinant or synthetic DNA** (complete Section II)

\_\_\_ **Use or creation of lentiviral vectors** (complete Section III)

\_\_\_ **Risk Group 2 Organisms** (complete Section IV)

\_\_\_ **Risk Group 3 Organisms** (complete Section V)

**Please list the names of the individuals who are covered under this protocol. Include their full name, title (faculty, post-doctoral, graduate and undergraduate students, visiting scientist, volunteer or staff), UTEP 800 ID number, and laboratory experience directly related to their role in experiments covered under the protocol.** All individuals must have the relevant experience and must have completed the current safety training in order to work under the protocol.

**Have you educated your staff regarding safe handling and decontamination procedures for all of the agents or materials listed in the protocol? [ ] Yes [ ]  No**

**Investigator Agreement:**

I attest 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.

As the Principal Investigator, I accept responsibility for making sure all laboratory personnel involved in the project have been appropriately trained. 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, 5thd 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 (747-7124) and the IBC Chair (747-8715) or IBC Coordinator (747-7007).**

Signature: Date: \_\_\_\_\_\_\_\_\_\_

Department Chair: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_

**SECTION II: RECOMBINANT OR SYNTHETIC DNA**

Complete SECTION II only if your project involves the creation of recombinant DNA, synthetic DNA or transgenic animals.

**Where will the recombinant or synthetic DNA experiments be performed?** (List all locations applicable and specify building and room number):

**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.**

**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.**

**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.**

**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.**

**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.**

**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.**

**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.**

**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.**

**Does your project include experiments involving more than 6 liters of culture** (Section III-D-6)?

 **[ ]  Yes [ ]  No.**

**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.**

**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.**

**What is the source of rDNA, DNA, RNA to be inserted or cloned?** (Include species of organism from which it is derived):

**What is the nature of rDNA, DNA, RNA to be inserted or cloned?** (For example is it a structural gene or oncogene?):

**What is the host system to be used**? (For example, Rat cardiomyocytes and HEK-293 cells; or E. coli strain BL21; or yeast):

**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):

**List any helper virus or packaging cells used?**  (For example 293FT cell line):

**Check the protective clothing and equipment used when handling this agent:**

**[ ]  Lab Coat and gloves [ ]  Centrifuge safety cups**

**[ ]  Lab Coat and double gloves [ ]  Booties and Hair Cover**

**[ ]  Chemical Fume Hood, Rm. location \_\_\_\_\_\_\_\_\_\_**

**[ ]  Biological Safety Cabinet, Rm. location \_\_\_\_\_\_\_**

**[ ]  N95 respirator [ ]  Surgical mask**

**[ ]  PAPR [ ]  Bio-bubble**

**[ ]  Safety glasses [ ]  Goggles**

**[ ]  Safety needles/scalpel [ ]  Blunt ended forceps/scissors**

**[ ]  Other \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Check the disinfectants used for surface decontamination and spills:**

**[ ]  Cavicide [ ]  Bleach**

**[ ]  Vesphene [ ]  70% alcohol**

**[ ]  Other \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Check the method of biohazardous waste disposal:**

**[ ]  Placed in red biohazard bag and autoclaved**

**[ ]  Chemical disinfection then placed in red biohazard bag**

**[ ]  Chemical disinfection of bulk liquid then poured down sanitary sewer**

**[ ]  Placed in black bag for incineration**

**SECTION III: LENTIVIRAL VECTORS**

Complete SECTION III only if your project involves the creation of lentiviral vectors.

See also, the NIH guidance document, Biosafety Considerations for Research with Lentiviral Vectors**,** <http://oba.od.nih.gov/rdna_rac/rac_guidance_lentivirus.html>

**Where will the experiments involving the use of lentivirus or lentiviral vectors be performed?** (List all locations applicable and specify building and room number):

**Describe the nature of the vector system and the potential for regeneration of replication competent virus from the vector components.**

**Describe the nature of the transgene insert** (e.g., known oncogenes or genes with high oncogenic potential may merit special care).

**Describe the anticipated vector titer and anticipated total amount of vector to be produced.**

**Describe the procedure for how the viral vector will be concentrated? Include safety procedure(s) to minimize risk.**

**How many batches will be produced from the original production batch (**more than one batch increases the probability of having a homologous recombination event occur**)?**

**Describe the inherent biological containment of the animal host, if relevant.**

**Will needles, glassware or other sharps be used while working with risk group 2 organisms?**

 **[ ]  Yes [ ]  No.**

If yes describe what precautions will be taken by the PI and lab personnel to minimize the exposure risk.

**Describe the potential for insertional mutagenesis in case of accidental needle stick.**

**SECTION IV: Risk Group 2 Organisms**

Complete SECTION IV only if your project involves the use of risk group 2 organism(s) and the experiments were NOT described in Sections II & III.

**Where will the experiments involving the use of Risk Group 2 agents be performed?** (List all locations applicable and specify building and room number):

**Provide agent Safety Data Sheet (SDS) if available (**Formerly known as Material Safety Data Sheets [MSDS]).

**Check the protective clothing or equipment used when handling this agent:**

**[ ]  Lab Coat and gloves [ ]  Centrifuge safety cups**

**[ ]  Lab Coat and double gloves [ ]  Booties and Hair Cover**

**[ ]  Chemical Fume Hood, Rm. location \_\_\_\_\_\_\_\_\_\_**

**[ ]  Biological Safety Cabinet, Rm. location \_\_\_\_\_\_\_**

**[ ]  N95 respirator [ ]  Surgical mask**

**[ ]  PAPR [ ]  Bio-bubble**

**[ ]  Safety glasses [ ]  Goggles**

**[ ]  Safety needles/scalpel [ ]  Blunt ended forceps/scissors**

**[ ]  Other \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Check the disinfectants used for surface decontamination and spills:**

**[ ]  Cavicide [ ]  Bleach**

**[ ]  Vesphene [ ]  70% alcohol**

**[ ]  Other \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Check the method of biohazardous waste disposal:**

**[ ]  Placed in red biohazard bag and autoclaved**

**[ ]  Chemical disinfection then placed in red biohazard bag**

**[ ]  Chemical disinfection of bulk liquid then poured down sanitary sewer**

**[ ]  Placed in black bag for incineration**

**Will needles, glassware or other sharps be used while working with risk group 2 organisms?**

 **[ ]  Yes [ ]  No.**

If yes describe what precautions will be taken by the PI and lab personnel to minimize the exposure risk.

**Will risk group two organisms be injected into animals? [ ]  Yes [ ]  No.**

**Can this agent infect or cause disease in immunocompromised individuals?** **[ ]  Yes [ ]  No**

 **If yes, provide a description of potential mechanism of laboratory transmission:**

**If Yes, is the infection associated with replication in humans or is it abortive (no progeny)?**

 **Replication [ ] , or abortive [ ]**

**Please list or describe any known vaccine or chemo prophylactic drugs available to treat infections from the proposed risk group 2 organisms?**

**SECTION V: Risk Group 3 Organisms**

Complete SECTION V only if your project involves the use risk group 3 organisms.

**Where will the experiments involving the use of Risk Group 3 agents be performed?** (List all locations applicable and specify building and room number):

**Provide agent Safety Data Sheet (SDS) if available (**Formerly known as Material Safety Data Sheets [MSDS]).

**Describe pathogenicity, including disease incidence and severity.**

**Describe route of transmission.**

**Describe agent stability.**

**What is the infectious dose?**

**What is the concentration (number of infectious organism per unit volume) and the volume of the concentrated material being handled?**

**What is the origin of the infectious material (may refer to geographic location, host or nature of source)?**

**Is there an effective prophylaxis or therapeutic intervention available?** Specify prophylaxis or therapeutic intervention.

**Is medical surveillance recommended prior to commencement of work?**

**What systems are you using to propagate or study the agent(s) listed?**

**Will needles, glassware or other sharps be used while working with risk group 3 organisms?**

 **[ ]  Yes [ ]  No.**

If yes describe what precautions will be taken by the PI and lab personnel to minimize the exposure risk.

**Will risk group 3 organisms be injected into animals? [ ]  Yes [ ]  No.**

**What is the availability of data from animal studies (pathogenicity, infectivity and route of transmission in animals)?**

**Check the disinfectants used for surface decontamination and spills:**

**[ ]  Cavicide [ ]  Bleach**

**[ ]  Vesphene [ ]  70% alcohol**

**[ ]  Other \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Check the protective clothing or equipment used when handling this agent:**

**[ ]  Closed front gown/ double gloves [ ]  Centrifuge safety cups**

**[ ]  Booties [ ]  Double Booties and Hair Cover**

**[ ]  Chemical Fume Hood, Rm. location \_\_\_\_\_\_\_\_\_\_**

**[ ]  Biological Safety Cabinet, Rm. location \_\_\_\_\_\_\_**

**[ ]  N95 respirator [ ]  Surgical mask**

**[ ]  PAPR [ ]  Bio-bubble**

**[ ]  Safety glasses [ ]  Goggles**

**[ ]  Safety needles/scalpel [ ]  Blunt ended forceps/scissors**

**[ ]  Other \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Check the method of biohazardous waste disposal:**

**[ ]  Placed in double red biohazard bag and autoclaved**

**[ ]  Placed in single 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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**Are there any blanks or information missing?** **[ ]  Yes [ ]  No.**

**Is the protocol written in lay terms?** **[ ]  Yes [ ]  No.**

**Has the biosafety office reviewed the submission?** **[ ]  Yes [ ]  No.**

**Has a primary reviewer been assigned?**  **[ ]  Yes [ ]  No.**

**NIH rDNA Category: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date Approved: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Approved Biosafety Level: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Signatures:**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**IBC Chair Biosafety Officer**

**Signatures of Individuals Covered Under This Protocol**

**Name Signature OHP Date GLS Date BBP Date**