The TCU Institutional Biosafety Committee (“IBC”) is responsible for overseeing the compliance of research and scholarly activities that are conducted by faculty, staff, students, and/or any other individuals at or under the auspices of TCU, and that involve the use of recombinant or synthetically derived nucleic acid molecules or other biohazardous materials.

Consult (1) [*NIH Guidelines for Research Involving Recombinant DNA Molecules*](http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines), (2) TCU’s Biosafety policy and procedures (3) [CDC’s *Biosafety in Microbiological and Biomedical Laboratories, 5th Edition*](https://www.cdc.gov/biosafety/publications/bmbl5/index.htm), (4) TCU’s Integrated Lab Management Plan for more information during completion of this application; and (5) TCU’s *Biohazard Recognition and Control: Guidelines for Handling Pathogenic Microorganisms & Disposing Biohazardous Waste* for more information.

**Instructions:**

* Use the most recent version of this form. Current versions may be found on the TCU Office of Research’s website at <https://research.tcu.edu/research-compliance/institutional-biosafety-committee/>.
* Sections 1, 6, and the Certification Statement must be completed for all protocols.

Sections 2-5 must be completed only where appropriate. Mark the applicable boxes below.

* SECTION 2: Recombinant and Synthetic Nucleic Acids
* SECTION 3: Microbes & Viruses

 SECTION 4: Biological Toxins

 SECTION 5: Human / Non-Human Primate Materials

* Submit the completed form, training certificates, SOPS, floor plans, and all other relevant documents through email at [IBC@tcu.edu](mailto:IBC@tcu.edu).
* The Principal Investigator will be advised of the Committee’s action through email.

There are multiple agents that the IBC oversees for research purposes at TCU. In some cases (e.g. recombinant nucleic acids) protocols will be exempted, however this determination is made by the IBC. **IN ALL CASES, NO WORK CAN BEGIN UNTIL APPROVAL (OR EXEMPTION) HAS BEEN COMPLETED**.

***Expiration:*** All protocols expire three years from the date of approval, if not earlier*, and all are* subject to Annual Continuing Review (after the first and second year of research/instructional activity). Within 30 days following the first and second anniversaries of the initial IBC approval, an Annual Animal Protocol Review application must be submitted to the IBC. If activity is *desired* to be continued beyond the third anniversary, a new Protocol Application (this form) must be submitted for review.

***Amendment*:** Proposed changes to active protocols should be submitted to the IBC using the Protocol Amendment application form.

Questions? Please contact the Institutional Biosafety Committee at [IBC@tcu.edu](mailto:IBC@tcu.edu).

*Research Administration Use:*

Protocol #

Status:  Exempt

Non-Exempt



**Section 1 - General Information**

* 1. Principal Investigator

|  |  |
| --- | --- |
| **Principal Investigator (“PI”)**  (TCU Faculty only) | Name:       Telephone Number:  Email: |
| **PI’s Department** |  |
| **Project Title/Course Name/Number:** |  |
| **Emergency Contact Information:** Parties listed in this section must be listed as project personnel. | Name:       Telephone Number:  Alternate Name:       Telephone Number: |

* 1. Co-Principal Investigator (Co-PI): *TCU faculty, graduate students*

|  |  |  |
| --- | --- | --- |
| **Name and Department** |  |  |
| **Name and Department** |  |  |

* 1. List all personnel working on this project, their roles and responsibilities. Attached CITI training certificates to final submission.

|  |  |  |
| --- | --- | --- |
| Name | Title (research tech, student, etc.) | Role and responsibilities |
|  |  |  |
|  |  |  |
|  |  |  |

* 1. Research Location(s):

|  |  |  |
| --- | --- | --- |
| Building & Room | Current Laboratory BSL (only levels 1 and 2 are permitted at TCU currently) | Date Last Inspected by IBC |
|  |  |  |

* 1. Funding Agency/ Grant / Contract Number (Please attach copy of grant abstract):
  2. Please describe any actual or potential Conflict of interest:
  3. Proposed start date:       Proposed end date:
  4. Please provide a general description (in layperson’s language) of the experiments to be conducted, including a description of any significant risks if appropriate.

     

* 1. Attach appropriate SOPs for this specific protocol (SOPs signed and dated by the PI are required in the laboratory).
  2. Attach a floor plan of each laboratory covered by this application, showing the location of hazardous materials stored (bio-,Chemical, and radioactive hazards). Include locations of laboratory benches, desks, laboratory hoods, fire extinguishers, spill control supplies, and any other items to assist emergency response personnel. The floor plan(s) may be a hand-drawn sketch.
  3. Research Classification / Type (Check all that apply):

☐ Recombinant or synthetic Nucleic Acids

☐ Microorganisms

☐ Viruses

☐ Human Materials

☐ Non-Human Primate Materials

☐ Non-Primate Animals Materials

☐ Vertebrate Animals

☐ Invertebrate Animals

☐ Plants

☐ Biological toxic

* 1. Is this protocol required for an IACUC protocol?

☐ Yes ☐ No

* 1. Is this protocol required for an IRB protocol?

☐ Yes ☐ No

* 1. Does the research involve the movement of biological materials between, to and/or from designated laboratory space(s)?

**SECTION 2 - RECOMBINANT AND SYNTHETIC NUCLEIC ACIDS**

2.1 Please provide the following information.

|  |  |  |  |
| --- | --- | --- | --- |
| Nature/Source(s) of Inserted DNA Sequences:  include genus/species, name of protein pathway, etc. | Describe the intended use of the rDNA and the function / activity of the DNA or its product.  Examples – new protein expression, cloning, transgenic generation, etc. | Hosts for propagation:  Examples - E. coli K-12, HeLa Cells, Mouse  *Note:* This corresponds to both the production of rDNA and the species into which it will be introduced – include all. | Method of Gene Transfer/Vector(s):  Examples - plasmid, virus, amplicons or transposons, naked DNA, conjugation, chemical, etc. |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

2.2 Exemption Determination

*NIH Guidelines* provide a description of recombinant/synthetic nucleic acid experiments that are considered exempt. TCU requires registration of Exempt experiments through submission of Sections 1, 2.1 and 2.2, and the certification statement page of this Application. Non-Exempt research requires completion of the remainder of this Application. The information below will help to make the Exempt/Non-Exempt determination.

**A.** The following experiments do not qualify for exemption under the NIH Guidelines, and will require submission of this protocol application in its entirety.

* Deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally (see [Section V-B, Footnotes and References of Sections I-IV](http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.html#_Toc446948371)), if such acquisition could compromise the ability to control disease agents in humans, veterinary medicine, or agriculture.
* Deliberate formation/cloning of recombinant or synthetic nucleic acid molecules containing genes for the biosynthesis of toxin molecules lethal for vertebrates at an LD50 of less than 100 nanograms per kilogram body weight (e.g., microbial toxins such as the botulinum toxins, tetanus toxin, diphtheria toxin, and *Shigella dysenteriae* neurotoxin).
* Human gene transfer- the deliberate transfer into human research participants of either:

1. Recombinant nucleic acid molecules, or DNA or RNA derived from recombinant nucleic acid molecules, or

2. Synthetic nucleic acid molecules, or DNA or RNA derived from synthetic nucleic acid molecules, that meet any one of the following criteria:

a. Contain more than 100 nucleotides; or

b. Possess biological properties that enable integration into the genome (e.g., *cis* elements involved in integration); or

c. Have the potential to replicate in a cell; or

d. Can be translated or transcribed.

* Experiments using [Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents](http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.html#_Toc446948379) as host-vector systems.
* Experiments in which DNA from [Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents](http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.html#_Toc446948379) is cloned into nonpathogenic prokaryotic or lower eukaryotic host-vector systems.
* 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.
* Experiments involving transgenic animals other than rodents. (Transgenic = genome has been altered by stable introduction of recombinant or synthetic nucleic acid molecules, or nucleic acids derived therefrom, into the germ-line)
* Experiments involving transgenic or knockout rodents requiring containment *above* [BL1](http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.html#_Toc446948435).
* Experiments involving testing of viable recombinant or synthetic nucleic acid molecule-modified microorganisms on whole animals.
* Experiments to genetically engineer plants by recombinant or synthetic nucleic acid molecule methods, to use such plants for other experimental purposes (e.g., response to stress), to propagate such plants, or to use plants together with microorganisms or insects containing recombinant or synthetic nucleic acid molecules.
* Experiments involving more than 10 L of culture.
* Experiments with influenza viruses generated by recombinant or synthetic methods (e.g., generation by reverse genetics of chimeric viruses with reassorted segments, introduction of specific mutations).

***If your research meets one or more of the experiment types described above, please complete the remainder of this Protocol Application for Non-Exempt research. If your research does not meet any of the descriptions above, it may qualify as Exempt - proceed to the next question.***

**B.** In Table 1 below, please select all exempt categories that apply to your research Once completed, move on to the certification statement page.

Table 1. Exempt Experiments under NIH Guidelines, Section III-F.

|  |  |
| --- | --- |
|  | Exemption 1: Synthetic nucleic acids that: (1) can neither replicate nor generate nucleic acids that can replicate in any living cell (e.g., oligonucleotides or other synthetic nucleic acids that do not contain an origin of replication or contain elements known to interact with either DNA or RNA polymerase), and (2) are not designed to integrate into DNA, and (3) do not produce a toxin that is lethal for vertebrates at an LD50 of less than 100 nanograms per kilogram body weight.  If a synthetic nucleic acid is deliberately transferred into one or more human research participants and meets the criteria of [Section III-C](http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.html#_Toc446948322), it is not exempt under this Section. |
|  | Exemption 2: Recombinant/synthetic nucleic acid molecules that are not in organisms, cells, or viruses and that have not been modified or manipulated (e.g., encapsulated into synthetic or natural vehicles) to render them capable of penetrating cellular membranes. |
|  | Exemption 3: Recombinant/synthetic nucleic acid molecules that consist solely of the exact recombinant or synthetic nucleic acid sequence from a single source that exists contemporaneously in nature. |
|  | Exemption 4: Recombinant/synthetic nucleic acid molecules that consist entirely of nucleic acids from a prokaryotic host, including its indigenous plasmids or viruses when propagated only in that host (or a closely related strain of the same species), or when transferred to another host by well-established physiological means. |
|  | Exemption 5: Recombinant/synthetic nucleic acid molecules that consist entirely of nucleic acids from a eukaryotic host including its chloroplasts, mitochondria, or plasmids (but excluding viruses) when propagated only in that host (or a closely related strain of the same species). |
|  | Exemption 6: Recombinant/synthetic nucleic acid molecules that consist entirely of DNA segments from different species that exchange DNA by known physiological processes, though one or more of the segments may be a synthetic equivalent.  A list of such exchangers will be prepared and periodically revised by the NIH.  See [Appendices A-I through A-VI](http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.html#_APPENDIX_A._EXEMPTIONS), *Exemptions under Section III-F-6--Sublists of Natural Exchangers*, for a list of natural exchangers that are exempt. |
|  | Exemption 7: Those genomic DNA molecules that have acquired a transposable element, provided the transposable element does not contain any recombinant and/or synthetic DNA. |
|  | Exemption 8: Recombinant/synthetic nucleic acid molecules that do not present a significant risk to health or the environment, as determined by the NIH. See NIH Guidelines [Appendix C](http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.html#_APPENDIX_C._EXEMPTIONS) for more details on each type of experiment. Under this category, please select the option(s) below pertaining to your experiment(s):  Recombinant or synthetic nucleic acid molecules containing less than one-half of any eukaryotic viral genome (all viruses from a single family being considered identical -- see [Appendix C-IX-E](http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.html#_Appendix_C-VIII._Footnotes), *Footnotes and References of Appendix C*), that are propagated and maintained in cells in tissue culture **except for those** listed in [Appendix C-I-A](http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.html#_Appendix_C-I-A._Exceptions).  Experiments which use *Escherichia* *coli* K-12 host-vector systems, **with the exception** of those experiments listed in [Appendix C-II-A](http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.html#_APPENDIX_C._EXEMPTIONS), provided that:  (i) the *Escherichia* *coli* host does not contain conjugation proficient plasmids or generalized transducing phages; or (ii) lambda or lambdoid or Ff bacteriophages or non-conjugative plasmids (see [Appendix C-IX-B](http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.html#_Appendix_C-VII._Footnotes), *Footnotes and References of Appendix C*) shall be used as vectors.  Experiments involving the insertion into *Escherichia* *coli* K-12 of DNA from prokaryotes that exchange genetic information (see [Appendix C-IX-C](http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.html#_Appendix_C-IX._Footnotes), *Footnotes and References of Appendix C*) with *Escherichia* *coli* may be performed with any *Escherichia* *coli* K-12 vector (e.g., conjugative plasmid).  When a non-conjugative vector is used, the *Escherichia* *coli* K-12 host may contain conjugation-proficient plasmids either autonomous or integrated, or generalized transducing phages.  Experiments involving Saccharomyces cerevisiae and Saccharomyces uvarum host-vector systems, **with the exception** of experiments listed in [Appendix C-III-A](http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.html#_APPENDIX_C._EXEMPTIONS).  Experiments involving *Kluyveromyces lactis*host-vector systems, **with the exception** of experiments listed in [Appendix C-IV-A](http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.html#_APPENDIX_C._EXEMPTIONS), provided laboratory-adapted strains are used (i.e. strains that have been adapted to growth under optimal or defined laboratory conditions). Any asporogenic *Bacillus subtilis* or asporogenic*Bacillus licheniformis* strain which does not revert to a spore-former with a frequency greater than 10-7 may be used for cloning DNA with the exception of those experiments listed in[**Appendix C-V-A**](http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.html#_APPENDIX_C._EXEMPTIONS)**.** **Recombinant or synthetic nucleic acid molecules derived entirely from extrachromosomal elements of the organisms listed below (including shuttle vectors constructed from vectors described in**[**Appendix C**](http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.html#_APPENDIX_C._EXEMPTIONS)**), and *propagated and maintained* in the organisms listed below. Exceptions exist and are listed in** [**Appendix C-VI-A**](http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.html#_APPENDIX_C._EXEMPTIONS)**.**    Use of BL1 Transgenic/Knockout Rodents – The purchase or transfer of transgenic/knockout rodents maintained at BL1 containment is exempt. Subsequent use of these animals is also exempt providing the experimental protocol does not involve the use of recombinant DNA.  Generation (breeding) Transgenic/Knockout Rodents – Breeding of transgenic/knockout rodents from one strain and at BL1 containment is exempt. The breeding of two different transgenic/knockout rodents or the breeding of a transgenic/knockout rodent and a non-transgenic rodent with the intent of creating a new strain is exempt if:  (1) Both parental rodents can be housed under BL1 containment; **and**  (2) neither parental transgenic rodent contains the following genetic modifications:  (i) incorporation of more than one-half of the genome of an exogenous eukaryotic virus from a single family of viruses; or (ii) incorporation of a transgene that is under the control of a gammaretroviral long terminal repeat (LTR); **and**  (3) the transgenic rodent that results from this breeding is not expected to contain more than one-half of an exogenous viral genome from a single family of viruses. |

2.3. Non-Exempt rDNA Experiments. If your project involves experiments that are not clearly *Exempt* as described in Section 2.2 of this document, please proceed with this section.

Table 1. Non-Exempt Experiments. Please complete Table 1. Use one table for each source of DNA. Attached additional copies of the table, if necessary.

|  |  |  |
| --- | --- | --- |
| **RECOMBINANT INSERT (TRANSGENE) AND VECTORS** | | |
| Original source(s) of DNA/RNA sequences (include genus, species, gene name and abbreviation) |  | |
| Agent’s NIH Risk Group ([*NIH Guidelines*, Section II](http://www4.od.nih.gov/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm#_Toc7261553))  Note: Infectious/pathogenic materials must be registered with IBC | RG1  RG2  RG3  RG4 | |
| Nature of inserted sequences (include gene names, biological markers, sequences, etc. and describe the function/activity of the DNA or its product) |  | |
| Will the experiment involve use or production of more than 10L of culture of viable organisms containing rDNA? | Yes If yes, specify how you will meet the criteria of [*NIH Guidelines*, Appendix K](http://www4.od.nih.gov/oba/rac/guidelines_02/APPENDIX_K.htm) for Large Scale Use:  No | |
| Will the genetically modified organism (GMO) be released into the environment? | Yes If yes, describe:  No | |
| Is the inserted sequence or GMO harmful to humans or animals? | Yes Describe diseases or symptoms caused by agent and possible routes of exposure:  No  N/A | |
| Is the inserted sequence or GMO harmful to plants?  (See USDA’s [7 CFR 340](http://www.niehs.nih.gov/odhsb/biosafe/7cfr340.htm)) | Yes (please describe appropriate safeguards and address [7 CFR 340](http://www.niehs.nih.gov/odhsb/biosafe/7cfr340.htm))  No  N/A | |
| Physical containment as specified in *NIH Guidelines* [Section II](http://www4.od.nih.gov/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm#_Toc7261553) and [Appendix G](http://www4.od.nih.gov/oba/rac/guidelines_02/APPENDIX_G.htm). Please note: the CDC classifies work with human and non-primate blood, body fluids, or tissue (e.g. human cell culture) as a minimum of BL-2. | BL1  BL2 (BL3 and BL4 are prohibited at TCU)  and/or  Experiments Involving Plants:  BL1-P  BL2-P  BL3-P BL4-P  and/or  Experiments Involving Animals:  BL1-N  BL2-N  BL3-N  BL4-N | |
| Is a helper virus required? | Yes If yes, specify:  No | |
| For experiments involving a deliberate attempt to obtain expression of *a foreign gene*, identify what proteins will be produced and their biological activity (enter “none” if not applicable) |  | |
| **TARGET RECIPIENT** | | |
| Cultured Cells? | | Describe: |
| Animals? | | Describe: |
| Plants? | | Describe: |
| Humans? | | Describe: |
| Other? | | Describe: |
| **DUAL USE RESEARCH** (research intended to enhance scientific understanding and public health but could generate results that could be misused to advance biological weapon effectiveness) | | |
| Check any categories below that pertain to your project:  Renders a useful vaccine ineffective  Adds antibiotic resistance affecting response to a clinically useful drug  Enhances pathogen virulence  Widens a pathogen’s host range  Lets a pathogen evade diagnostic or detection modalities  Weaponization (e.g., environmental stabilization of pathogens) | | |

2.4. Source of insert DNA or rDNA. If biological, source is

* If a viable intact microbe or virus, complete Section3, Microbes and Viruses
* If human materials, complete Section 5, Human Materials

**Section 3 – Microbes and Viruses**

Complete this section for all uses of microbes and viruses except non-pathogenic E.coli (e.g., K-12 or DH5a), Bacillus subtilis, or Saccharomyces cerevisiae recipients in host-vector systems.

3.1. What agent(s) will be used in this project? Indicate the strain, serogroup or other type identification, as well as, noteworthy pathogenicity information (i.e. virulence factors).

3.2. Are the agents know to be pathogenic (includes opportunistic pathogenicity to:

Humans  Yes  No  Unknown

Animals  Yes  No  Unknown

Plants  Yes  No  Unknown

Explain as necessary. Indicate attenuation or virulence factors as appropriate.

3.3. Is the agent on the [CDC Select Agent List](https://www.selectagents.gov/SelectAgentsandToxinsList.html):  Yes  No

If yes, submit a copy of your approval from the APHIS/CDC Form 1 with this application.

**Section 4 – Biological Toxins**

Complete this section if you are working with a biological toxin that is listed as a select agent or your work involves the biosynthesis of toxic molecules covered by the select agents guidelines. NOTE: Routine operations with any toxin are to be conducted under BSL-2 conditions with the aid of PPE and well-maintained engineering controls (See BMBL, page 386). SOPs must be in place.

4.1. Identify the toxin(s) to be used, their source, and all locations where they will be produced, stored and/or handled.

4.2. Is the toxin on the [CDC Select Agent List](https://www.selectagents.gov/SelectAgentsandToxinsList.html):  Yes  No

4.3. Will the research involve the shipping to/from TCU or movement of biological materials, to and/or from designated laboratory space(s)? NOTE: Transport of most biological materials is federally regulated. Please check with Risk Management if you are unsure about proper transport.

Yes

No

**Section 5 - Human/Non-Human Primate Materials**

Complete this section if you are working with human or non-human primate materials or materials of human / non-human primate origin

5.1. Proposed research will include materials from:

5.2. Indicate the nature of the materials to be used:

Blood/blood components

Body fluids/excretions

Cell lines (immortal)

Cell lines (non-immortal)

Sell lines (primary)

Non-preserved tissues

Other

5.3. Briefly describe the materials. Specify cell lines, origin/distributor, testing and/or purification measures, known contaminants, etc.

5.4. Have all personnel involved with the project received documented initial training in the procedures for safe handling of the material including the proper use of protective equipment and an explanation of the [TCU Bloodborne Pathogen Exposure Control Program?](http://tcusafety.tcu.edu/wp-content/uploads/2014/09/Written-Exposure-Control-Plan.pdf)

Yes  No

5.5. Have personnel working with these materials been offered a hepatitis B vaccine?

Yes  No

**Section 6 - Risk Management**

6.1. Engineering controls: Select the engineering controls used (check all that apply) and provide the requested information associated with each control checked.

Biological Safety Cabinet

* Type of cabinet:
* Last inspection date:
* Ducted to the building:  Yes  No
* Location (building and room number):

Fume Hood

* Last inspection date:

Centrifuge Safety Cups and/or sealable rotor

Other engineering control. Describe:

6.2. Sharps: e.g., syringes, scalpels, probes, etc.

a. Will sharps be used in the above indicated research?  Yes  No

b. Are sharps containers available and used in immediate area where sharps are

handled?  Yes  No

c. Are needles used in the laboratory?  Yes  No

6.3. Personal Protective Equipment:

|  |  |
| --- | --- |
| Select the PPE required for your research (check all that apply) | Cover Sleeves  Tyvek suit  Bonnet, hair cover  Surgical mask  Splash googles  Globes  Lab coat  Disposable gown  N-5 or N-10 Respirators (Training and fit- testing are required)  Safety glasses  Face shield  Shoe covers  Other |
| For Gloves, indicate all that apply. A specific thickness may be mentioned in other | Nitrile  Latex  Vinyl  Thermal protective  other |

6.4. Decontamination / Disinfection. S

a. elect the method(s) of decontamination and disinfection used (check all that apply)

and provide the requested information associated with each control checked.

Autoclave

* + Indicate the autoclave settings used with biowaste (time in minutes and temperature in Celsius):

Bleach solution

* + Indicate dilution(s):
  + Frequency in which dilutions are prepared:

Other engineering control. Describe:

b. Is/are the liquid disinfectants(s) registered with the EPA as effective against the

agent(s)?  Yes  No

c. Does the material to be disinfected have a high organic content (e.g., serum, proteins,

etc.)?  Yes  No

d. Will mixed waste(s) be generated?  Yes  No

e. How will routine cleaning of the lab space and equipment be performed? How Often?

6.5. Is the Laboratory (s) posted with BIOHAZARD warning sign?  Yes  No

6.6. Are these sites where the agents are incubated or stored posted with BIOHAZARD

warning signs?  Yes  No

6.7. Indicate emergency procedures in the event of personnel exposure (inhalation,

ingestion, inoculation, etc.)

6.8. Indicate emergency procedures in the event of a spill or release not involving personnel

exposure (contain spill)

6.9. Principle Investigator’s Assessment of Risk

a. What is/are the 1) most serious and 2) most probable adverse event(s) you can

foresee as a result of your research(for example: recombination, employee exposure,

etc.)?

b. How will you mitigate these risks?

6.10. Medical Surveillance:

a. Are there recommended prophylactics for the agents(s) described on this application?

Yes  No

b. Do you, the PI, think the proposed research warrants a laboratory medical surveillance program or do you currently have a medical surveillance program in place?  Yes  No

6.11. Hazardous Materials: list all labs where work will take place, and check the appropriate box(es) if the lab contains any of the materials

|  |  |
| --- | --- |
| Building and Room # |  |
| Recombinant DNA |  |
| Infectious Agents |  |
| X-ray |  |
| Lasers |  |
| Radioactive Materials |  |
| Animals |  |
| Hazardous Chemicals |  |
| Human Blood, Fluids, Tissue |  |

\*\* Copy and paste the above table here to add additional labs

6.13. Reference Materials: Please note the location of laboratory safety information below.

The location of this information should be communicated to all laboratory personnel.

a. Biohazard risk, containment, and disposal procedures

b. Location of Lab Emergency Plan (Specific to PI’s protocol/experiments):

c. Posted contact information for research-related accidents, injuries, or emergencies:

6.14. Lab security: Describe the procedures for site security (How will lab access be limited?

How will lab entries be kept secure? Will anyone have access besides personnel listed in

the protocol?)

**CERTIFICATION STATEMENT**

By signing below, I understand and accept the following obligations in this study:

* I affirm that all information contained in this document is accurate and complete.
* I recognize that as the principal investigator it is my responsibility to ensure that this research and the actions of all project personnel involved in conducting the study will conform with the IBC approved protocol and the provisions of the *NIH Guidelines for Research Involving Recombinant DNA*, the *CDC/NIH Biosafety in Microbiological and Biomedical Laboratories* manual, and the *Select Agent Rule* where appropriate.
* I will inform the IBC of any unanticipated biosafety related problems encountered while doing the research.
* I will notify the IBC of any change in a BSL-1 protocol.
* I will not initiate any change in a BSL-2 protocol without prior IBC approval.
* I will maintain all required research records on file and I recognize that representatives of the IBC are authorized to inspect these records.
* I accept responsibility for the safe conduct of the experiments to be conducted and will see that all associated personnel are trained in the safe laboratory practices required for this work. CITI IBC training courses will be completed by the PI, co-PI(s) and all listed researchers as required (see below).
* I will oversee the development and implementation of standard biosafety operating procedures for the laboratory.
* I understand that IBC approval is valid for 3 years and an annual IBC update is required in order to maintain approved status.
* I accept responsibility that all personnel working in my laboratory will be trained to report any biological spill to me and that any spills involving the contamination of personnel and/or the environment that has the potential to cause illness or may cause sufficient concern to the public will be reported to the IBC within the regulatory deadlines specified.
* I will instruct employees to report to me, or in my absence to TCU Risk Management, any infection where a potential exists that the infection may have been occupationally acquired.
* I understand that failure to comply with all NIH regulations, IBC requirements/policies, and the provisions of the protocol as approved by the IBC may result in suspension or termination of my research project.

For protocols involving the **use of Select Agents** (as defined in 42 CFR Part 73):

* I will comply with the requirements for the reporting and securing of select agents that fall within the bounds of 42 CFR Part 73.

For protocols using **animals in research**:

* I will contact the IACUC and submit an IACUC protocol to address relevant operational biocontainment and safety issues for the use of these agents in animals, prior to their introduction into animals. IBC protocol approval is required prior to IACUC protocol approval. I acknowledge that I must not start any research involving animals and biohazards without both an IBC and IACUC approval.

For protocols **requiring the purchase or transfer of tangible research materials** including, but not limited to, animals, reagents, plasmids, vectors and cell lines.

* Where an MTA is not established through the purchase, I understand the requirements and will submit a Material Transfer Agreement (MTA) request to Research Compliance at research@tcu.edu
* I will complete an MTA for the materials listed in the application prior to obtaining the materials
* I acknowledge that compliance to renew the MTA(s) or to comply with MTA-specified termination conditions at the end of the MTA approval period are the responsibility of the PI and will undertake these activities when needed.

|  |  |  |
| --- | --- | --- |
| Signature of PI |  | Date |

**Risk Management Certification & Signature**

The Risk Management Office must certify all Biosafety Level 2 laboratories before research commences. Please contact Risk Management at (817) 257-5395 or r.adickes@tcu.edu to make an appointment to certify your lab and/or biosafety cabinets used in this research protocol. (This process may occur simultaneously with submission and IBC review of your protocol, but Risk Management must provide final sign-off below before research can commence.)

By signing below, I hereby certify that the facilities are in accordance with the regulations and/or recommendations in (1) [*NIH Guidelines for Research Involving Recombinant DNA Molecules*](http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines), (2) TCU’s Biosafety policy and procedures (3) [CDC’s *Biosafety in Microbiological and Biomedical Laboratories, 5th Edition*](https://www.cdc.gov/biosafety/publications/bmbl5/index.htm), (4) TCU’s Integrated Lab Management Plan for more information during completion of this application; and (5) TCU’s *Biohazard Recognition and Control: Guidelines for Handling Pathogenic Microorganisms & Disposing Biohazardous Waste* for more information.

**Risk Management Specialist Date**