Biological Use Authorization Application

|  |
| --- |
| This application is for new research projects and renewals of research projects that involve rDNA and biohazards, and therefore require Biological Use Authorization (BUA) from the Institutional Biosafety Committee (IBC).1. Complete all questions of this BUA Application as they apply to your research project. The Chapman University Biosafety and Chemical Hygiene Manuals will help you complete this application. Additionally, it is recommended that you consult both the CDC’s current edition of [Biosafety in Microbiological and Biomedical Laboratories](http://www.cdc.gov/biosafety/publications/bmbl5/) and [The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules](http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines) (aka NIH Guidelines).
2. Submit your completed application and supplemental documents to EH&S. Determination of whether your research is eligible for expedited administrative review or needs to be reviewed by the Institutional Biosafety Committee will be made by the university biosafety officer upon receipt.
3. Assistance is available from the university biosafety officer, who can be contacted through EH&S. EHS@chapman.edu or 714.516.7199
 |

General Project Information

|  |  |  |
| --- | --- | --- |
| Type | [ ] New | Project Title       |
| [ ] Renewal: BUA#       |
|  | Name | Phone | Chapman email | Advanced Degree(s) | Title |
| Principal Investigator |       | 714.   .     |             |            |       |
| Lab Contact if different than PI |       | 714.   .     |       |       |       |
| Department       | College       |
| IACUC Protocol Number(s) |       | IRB Number(s)       |
| Funding Source(s)       |  |
| [ ] Yes [ ]  No | Does the funding sponsor require Chapman University EH&S review prior to submission to the sponsor?  |
| [ ] Yes [ ]  No | Do you have/need permits for this project (e.g., [USDA-APHIS](http://www.aphis.usda.gov/animal_health/vet_biologics/publications/CurrentProdCodeBook.pdf), [CDC](http://www.cdc.gov/od/eaipp/importApplication/agents.htm))? If Yes, specify and submit permit with this application:       |

Research Description

1. Describe in two or three paragraphs the work to be conducted in your laboratory directly related to recombinant or synthetic nucleic acid molecules and biohazardous agents. Include a brief, yet complete description of the various laboratory procedures. (<350 words)

1. Provide a declaration of what you consider to be the element(s) of your research that constitutes the greatest biohazard, and why.

# Hazard Identification

|  Human Research ParticipantsDoes this project involve human research participants? |
| --- |
| [ ]  Yes, this project involves human research participants. Please select appropriate box(es) below.[ ]  No, this project does not involve human research participants. Skip the remainder of this subsection. |
|  | **Yes** | **No** |  |
|  | [ ]  | [ ]  | This project involves human gene transfer as defined under [NIH Guidelines, Section III-C-1](http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.html#_Toc351276235). |
|  | [ ]  | [ ]  | This project involves administration of recombinant or synthetic nucleic acids to human research participants, even if exempt under NIH Guidelines.If Yes to either of the above, submit the following as they apply:1. This application
2. Completed NIH Guidelines, Appendix M-I-A
3. All correspondence with NIH Office of Biotechnology Activities (OBA) Recombinant DNA Advisory Committee (RAC)
4. Clinical protocol
5. Investigator brochures
6. PI’s Curriculum Vitae, in PHS-398 format
7. Proposed consent forms
8. IRB approval: IBC approval is required prior to IRB approval for new projects. Provide IRB approval for renewals.
 |

| Animal ResearchDoes this project involve animal research subjects? |
| --- |
| [ ]  Yes, this project involves animal research subjects. Select appropriate box(es) below and **provide details**.[ ]  No, this project does not involve animal research subjects. Skip the remainder of this subsection. |
|  | Yes | No |  |
| a | [ ]  | [ ]  | Laboratory animals:       |
| b | [ ]  | [ ]  | Immunodeficient animals:       |
| c | [ ]  | [ ]  | Wild animals:       |
| Please contact the Institutional Animal Care and Use Committee for authorization to work with animals, iacuc@chapman.edu. |

| Tissue, Blood, and Body FluidsDoes this project involve tissues, blood, or body fluids? **Primary cell isolates and/or cell lines are included.** |
| --- |
| [ ]  Yes, this project involves tissues, blood, body fluids. Please provide additional details in the table below.[ ]  No, this project does not involve tissues, blood, body fluids. Skip this subsection. |

|  | Tissue Culture Table |
| --- | --- |
| List all cell lines or eukaryotic cells including commercially available human cell lines (e.g. CHO, COS, or HEK 293) to be used. All human and non-human primate primary isolate and cell lines must be handled with BSL2 precautions. |
| **a. Cell Line/Primary isolate** | **b. Species of Origin and Organ** | **c. Source****Company/Collaborator** | **d. Tested for pathogens\*? If yes, which pathogens and status?** | **e.** [**Risk Group**](http://www.absa.org/riskgroups/) **(Biosafety)** |
| HeLaEXAMPLE | Homo sapiens, cervix | ATCC | [ ] No (Not tested)  [x] Yes: Cells contain human papilloma virus | [ ]  RG 1[x]  RG 2 |
|       |       |       | [ ] No (Not tested)  [ ] Yes:         | [ ] RG 1[ ] RG 2 |
|       |       |       | [ ] No (Not tested)  [ ] Yes:         | [ ] RG 1[ ] RG 2 |
|       |       |       | [ ] No (Not tested)  [ ] Yes:         | [ ] RG 1[ ] RG 2 |
|       |       |       | [ ] No (Not tested)  [ ] Yes:         | [ ] RG 1[ ] RG 2 |

\*Pathogen testing is not required, but please note if known.

If you need additional spaces, include multiple copies of this table.

| Bloodborne Pathogens |
| --- |
|  | Yes | No |  |
|  | [ ]  | [ ]  | This project involves drawing, processing, working with, or storing human blood, tissue, cells, cell lines, or body fluids visibly contaminated with blood or other potentially infectious materials (OPIM). If Yes, the [California Bloodborne Pathogens (BBP) Rule](https://www.dir.ca.gov/title8/5193.html) and Federal Bloodborne Pathogen Standard apply. BBP program requirements include completion of the following:1. Annual Bloodborne Pathogens for Researchers training. Please complete before submitting this application.
2. Site-specific BBP Exposure Control Plan if required: **Submit with this application.**
 |

|  |
| --- |
| Bacteria, Viruses, Fungi, Parasites, and PrionsDoes this project involves research with infectious agents such as bacteria, viruses, fungi, parasites, or prions? |
| [ ]  Yes, this project involves infectious agents. Please provide additional details in the table below.[ ]  No, this project does not involve infectious agents. Skip this subsection. |

|  | Microorganism Table |
| --- | --- |
| List all bacteria, virus, rickettsia, yeasts, fungi, parasites, and prions.  |
| **a. Genus/Species/ Strain** | **b. Antibiotic resistant?** | **c. Administered to cells?** **(specify species)** | **d. Administered to animals or plants?** **(specify species)** | **e. Routes of potential occupational exposure include the following:** | **f. Susceptible species include the following:** | **g.** [**Risk Group**](http://www.absa.org/riskgroups/)**(Biosafety)** |
| *Pseudomonas aeruginosa* PAOMSEXAMPLE | [x] Yes: ceftazidime[ ] No | [x] Yes: human cells[ ] No | [x] Yes, wild type: Mice     [ ] Yes, transgenic:      [ ] No | [x] Aerosol[ ] Fecal/oral[x] Mucous membrane[ ] Other:       | [x] Humans [x] Animals[ ] Plants[ ] Other:       | [ ] RG 1[x] RG 2 |
|       | [ ] Yes:      [ ] No | [ ] Yes:      [ ] No | [ ] Yes, wild type:      [ ] Yes, transgenic:      [ ] No | [ ] Aerosol[ ] Fecal/oral[ ] Mucous membrane[ ] Other:       | [ ] Humans [ ] Animals[ ] Plants[ ] Other:       | [ ] RG 1[ ] RG 2 |
|       | [ ] Yes:      [ ] No | [ ] Yes:      [ ] No | [ ] Yes, wild type:      [ ] Yes, transgenic:      [ ] No | [ ] Aerosol[ ] Fecal/oral[ ] Mucous membrane[ ] Other:       | [ ] Humans [ ] Animals[ ] Plants[ ] Other:       | [ ] RG 1[ ] RG 2 |
|       | [ ] Yes:      [ ] No | [ ] Yes:      [ ] No | [ ] Yes, wild type:      [ ] Yes, transgenic:      [ ] No | [ ] Aerosol[ ] Fecal/oral[ ] Mucous membrane[ ] Other:       | [ ] Humans [ ] Animals[ ] Plants[ ] Other:       | [ ] RG 1[ ] RG 2 |

If you need additional spaces, include multiple copies of this table.

Yes No

1. [ ]  [ ]  Will the volume of bacterial cultures exceed 10 liters at one time?

| Transgenic Plants |
| --- |
| [ ]  Yes, this project involves transgenic plants. Please select appropriate box(es) below. **Provide genus and species**:      [ ]  No, this project does not involve transgenic plants. Skip the remainder of this subsection. |
|  | **Yes** | **No** |  |
| a. | [ ]  [ ]  | Does this project involve [Invasive species or noxious weeds](http://www.nwcb.wa.gov/). **If Yes, describe**:       |
| b. | [ ]  [ ]  | Do you have reason to believe that the proposed transgenic plants can survive in the immediate geographic area? **If Yes, describe**:       |
| **c.** | [ ]  [ ]  | Do you have reason to believe that the proposed transgenic plants can interbreed with regional native species or noxious weeds? **If Yes, describe**:       |
| **d.** | [ ]  [ ]  | Will any of your work involve plant pathogens? **If Yes, describe**:       |
| e. | [ ]  [ ]  | Harvest of, or work with, seeds and/or spores from transgenic plants. **If Yes, describe (provide genus, species):**            |
| f. | [ ]  [ ]  | Use of transgenic plants in greenhouse. **If Yes, describe**:        |
| g. | [ ]  [ ]  | Use of transgenic plants in the field. **If Yes describe**:       |

|  Recombinant and Synthetic DNA and RNA |
| --- |
| [ ]  Yes, this project does involve synhetic or recombinant nucleic acids. Please select appropriate box(es) below.[ ]  No, this project does not involve synhetic or recombinant nucleic acids. Skip remainder of this subsection.[ ]  Recombinant DNA procedures are limited to PCR amplification of DNA segments (i.e., no subsequent cloning of amplified DNA)? Skip the remainder of this subsection. |
| While answering these questions, you will find the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (aka ‘NIH Guidelines’) useful. NIH Guidelines are requirements, not merely guidelines. They can be found at http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines |
| Does this project involve any of the following? |
|  | **Yes** | **No** |  |
| a. | [ ]  | [ ]  | Construction and/or use of synthetic DNA/RNA (e.g., probes, DNA or RNA oligonucleotides, base-pair analogs).  |
| b. | [ ]  | [ ]  | Creation of cDNA/genomic libraries. **If Yes, list genus, species and strains.**     :       |
| c. | [ ]  | [ ]  | Use of recombinant or synthetic DNA/RNA in microorganisms that are exempt under NIH Guidelines, Section III-F. **If Yes, list genus, species and strains.**      |
| d. | [ ]  | [ ]  | Use of recombinant or synthetic DNA/RNA in non-exempt microorganisms. **If Yes, list genus, species and strains**:      |
| e. | [ ]  | [ ]  | Use of recombinant or synthetic DNA/RNA in animals. **If Yes, describe and list species:**       |
|  | \*Any research involving veterbrate animals will require separate application to the IACUC. Contact iacuc@chapman.edu.  |
| f. | [ ]  | [ ]  | Use of recombinant or synthetic DNA/RNA in plants (somatic cells or germ-line transgenics).**If Yes, describe and list species.**       |
| g. | [ ]  | [ ]  | Use of recombinant or synthetic DNA/RNA in cell culture.**If Yes, describe procedure and list species.**       |
| h. | [ ]  | [ ]  | Potential for toxic products to be produced/released from recombinant cells, animals, or plants. The definition of toxic is an agent with an LD50 of less than 100 nanograms per kilogram (ng/kg) body weight. **If Yes, list the toxic product(s) and how it functions**.       |
| i. | [ ]  | [ ]  | Potential for infectious agents to be produced/released from recombinant cells, animals, or plants. **If Yes, explain.**       |
| j. | [ ]  | [ ]  | Environmental release or field-testing of genetically engineered organisms.**If Yes, explain.**       |
|  |  |  |

If you have marked 'Yes' to any question a-j, complete the Gene Delivery Methods table (next page).

| Gene Delivery Methods Table |
| --- |
|  | List all gene delivery methods in the table below as they apply to gene transfer experiments and as they apply to the use of recombinant cells and microorganisms (engineered in your laboratory or obtained from another source). For large numbers of genes, attach a complete list of genes.  |
| **a. Gene Delivery Method**  | **b. Biological source of DNA****Use common** [**RefSeq**](http://www.ncbi.nlm.nih.gov/refseq/rsg/) **gene names** | ***c. In vitro*** **Specify cell type and activities**  | ***d. In vivo*****Specify species and activities** | **e. Source** |
|  **EXAMPLE**Electroporation | GFP, viral LTR | grown in human cells; PCR analysis | [ ] No [x] Yes:IV injection into mice |    |
|   |  |        | [ ] No [ ] Yes:       |        |
|   |  |       | [ ] No [ ] Yes:       |        |
|   |  |       | [ ] No [ ] Yes:       |        |
|   |  |        | [ ] No [ ] Yes:       |        |
|   |  |       | [ ] No [ ] Yes:       |        |
|   |  |       | [ ] No [ ] Yes:       |        |
|   |  |       | [ ] No [ ] Yes:       |        |

If you need additional spaces, include multiple copies of this table.

1. **Viral Vectors**

If human viral vectors are used complete the following:

 Yes No

|  |  |  |  |
| --- | --- | --- | --- |
| a.  | [ ]  | [ ]  | Negative replication competent virus testing has been performed on the above viral vectors. If Yes, submit results.       |
| b.  | [ ]  | [ ]  | Viral vectors will be infectious to humans. If yes, will the infection be productive or limited?            |
| c.  | [ ]  | [ ]  | Are there any additional health effects such as seroconversion. If yes, explain?            |

| Gene TransferDoes this project involve the transfer of DNA between organisms? |
| --- |
| [ ]  Yes, this project involves gene transfer, select appropriate box(es) below.[ ]  No, this project does not involve the transfer of genes, skip the remainer of this subsection. |
| Do any of the genes involved in this research influence the following (references to the *NIH Guidelines* are given)? If Yes, explain. |
|  | Yes | No |  |
| a. | [ ]  | [ ]  | Release of biological toxins ([NIH Guidelines, Section III-B-1](http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.html#_Toc351276232) and [Appendix F](http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.html#_Toc351276342)):       |
| b. | [ ]  | [ ]  | Deliberate transfer of a drug resistance trait to a microorganism when such resistance could compromise the ability to control the disease agent in humans, veterinary medicine, or agriculture ([NIH Guidelines, Section III-A](http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.html#_Toc351276229)):       |
| c. | [ ]  | [ ]  | Increase of tropism ([NIH Guidelines, Appendix B-V](http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.html#_Toc351276308)):       |
| d. | [ ]  | [ ]  | Increase of virulence ([NIH Guidelines, Section II-A-3](http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.html#_Toc351276226)):       |

| Oncogenes and Tumor Suppressor GenesIs your gene a known or suspected oncogene or tumor suppressor gene?[ ]  Yes, this project involves a potential oncogene or tumor suppressor gene. Select appropriate box(es) below.[ ]  No, this project does not involve a potential oncogene or tumor suppressor gene, skip this subsection. |
| --- |
|  | **Yes** | **No** |  |
| a. | [ ]  | [ ]  | Do any of your proposed genes appear in the following databases (must use common [RefSeq](http://www.ncbi.nlm.nih.gov/refseq/rsg/) gene names)?1. [Cancer Gene Census](http://cancer.sanger.ac.uk/cosmic/census/tables?name=symbol)
2. [Mouse Retrovirus Tagged Cancer Gene Database](http://variation.osu.edu/rtcgd/index.html)

**If Yes, they are known oncogenes. List**:       |
| b. | [ ]  | [ ]  | Are any of your proposed genes described in the scientific literatures as oncogenes? **If Yes, list genes and describe**.       |
| c. | [ ]  | [ ]  | Do you have other reasons to believe that your proposed genes are oncogenes? **If Yes, list genes and describe reasons.**       |
| d. | [ ]  | [ ]  | Do you have reasons to believe that you are silencing or knocking out tumor suppressor genes? **If Yes, list and describe**.       |
| e. | [ ]  | [ ]  | If Yes to any of the four preceding questions, are there any extenuating circumstances you would like the IBC to consider when setting biocontainment levels for this work? **If Yes, describe.**      |

| Transgenic AnimalsDoes this project involve the use of genetically modified animals? **Note: Transgenic animals include vertebrates and invertebrates (e.g., Fruitflies, zebrafish, nematodes, mice, rats)**[ ]  Yes, this project involves genetically modified animals, select appropriate box(es) below.[ ]  No, this project does not involve transgenic animals, skip this subsection.**Yes No**a. [ ]  [ ]  This project involves breeding of genetically modified animals. **If yes, explain**:           b. [ ]  [ ]  This project involves the creation of transgenic animals. **If yes, explain:**           c. [ ]  [ ]  This project involves rodents that contain more than 50% of the genomi of an exogenous eukaryotic virus from a single virus family? **If yes, provide details**:           d. [ ]  [ ]  This project involves rodents where a transgene is under the control of a functional gammaretroviral long-termianl repeat (LTR). **If yes, provide details**:           e. [ ]  [ ]  There is the potential for toxic product to be produced/released from the animals. **If yes, explain**:           f. [ ]  [ ]  There is the possibility of Inactivation of a tumor-suppressor. **If yes, explain**:            |
| --- |

|  |
| --- |
| NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules |
| Select all sections of the NIH Guidelines that apply to this project. NIH Guidelines can be found at <https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf>.  |
|  | [ ]  |  | [Section III-A](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf) | Experiments that require IBC approval, RAC review and NIH Director approval before initiation (e.g., deliberate transfer of drug resistance to a microorganism that is not known to acquire it naturally, if such acquisition could compromise the ability to control disease agents in humans, animals or agriculture) |
|  | [ ]  |  | [Section III-B](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf) | Experiments that Require NIH/OBA and IBC Approval Before Initiation (e.g., cloning of toxin molecules with a LD50 less than 100 ng/kg) |
|  | [ ]  |  | [Section III-C](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf) | Experiments that require IBC and Institutional Review Board (IRB) approvals and RAC review before research participant enrollment (e.g., human gene transfer) |
|  | [ ]  |  | [Section III-D](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf) | Experiments that require IBC approval before initiation (e.g., recombinant and synthetic nucleic acids in pathogenic microorganisms, viral vectors for gene transfer, gene transfer in Risk Group 2 microorganisms) |
|  | [ ]  |  | [Section III-E](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf) | Experiments that require IBC registration before initiation (e.g., recombinant and synthetic nucleic acids in Risk Group 1 microorganisms or formulated into synthetic or natural vehicles, experiments involving whole plants at BSL-1P) |
|  | [ ]  |  | [Section III-F](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf) | Exempt experiments (e.g., recombinant and synthetic DNA that is not in organisms or viruses, DNA/RNA in microorganisms that are exempt under III-F) |

Hazard Control

| Physical Containment and Biosafety Level |
| --- |
|  | What biosafety level(s) are recommended for your work according to the NIH Guidelines and the CDC’s Biosafety in Microbiological and Biomedical Laboratories (BMBL)? |
|  | a. | [ ] Laboratory: | [ ]  BSL-1 | [ ]  BSL-2 | [ ]  BSL-2 w/3 practices |  |
|  | b. | [ ]  Animal Facility: | [ ]  ABSL-1 | [ ] ABSL-2 | [ ] ABSL-2 w/3 practices |  |
|  | c. | [ ]  Plant Facility: | [ ]  BSL-1P | [ ]  BSL-2P | [ ]  Field Work |  |
|  | Chapman University does not have the capacity to perform work requiring BSL-3 containment or higher. |

| Location for use and storage of infectious agents and recombinant DNA |
| --- |
| List each Chapman University research space where you will perform work with biohazardous agents or recombinant DNA. Identify specific buildings, rooms, and activities. |
| 1. ***In vitro* Use**
 |  |
| **Building/Room** | **Activities** | **Biohazardous Agents** | **Comments** |
| 9501 Rinker HSC, 241**EXAMPLE** | Cell culture of human cells, growth of lentiviral vectors, creation of transgenic plants | AAV, plasmids, human cells, transgenic plant seeds, Pseudomonas aeruginosa | BSL-2 tissue culture room. Certified biosafety cabinet in room. |
|       |       |       |       |
|       |       |       |       |
|       |       |       |       |
|       |       |       |       |
| 1. **Animal Use**
 |  |
| **Building/Room** | **Activities** | **Biohazardous Agents** | **Comments** |
| Hashinger Vivarium**EXAMPLE** | (e.g., implanting human cells in mice, perfusions of mice exposed to retrovirus, housing of exposed animals) | (e.g., human cell lines, murine cells transduced with gammaretroviral vectors) | BSL-2 tissue culture room. Certified biosafety cabinet in room. |
|       |       |       |       |
|       |       |       |       |
|       |       |       |       |
|       |       |       |       |
| 1. **Shared Core Facilities (e.g., MRI, FACS)**
 |
| **Facility/Building/Room** | **Activities** | **Biohazardous Agents** | **Comments** |
| 9501 Rinker HSC, 232**EXAMPLE** | (e.g., cell sorting, imaging of animals, flow cytometry) | (e.g., cell lines, animal cells from exposed animals, cells with recombinant DNA) |  |
|       |       |       |       |
|       |       |       |       |
|       |       |       |       |
|       |       |       |       |

1. Briefly describe any work environment that does not fit the above descriptions (e.g., field work):

| Equipment |
| --- |
|  | This project includes use of the following equipment with aerosol-generating potential: |
|  | [ ]  Centrifuge  | [ ]  Syringes/needles | [ ]  French press | [ ]  Homogenizer |
|  | [ ]  Cell sorter | [ ]  Sonicator  | [ ]  Other **specify**:       |
|  | This project includes use of the following equipment with engineered safety features. |
|  | [ ]  Biological safety cabinet | [ ]  Safety cups or sealed rotors for centrifuges |
|  | [ ]  Sharps  | [ ]  Splash shields |
|  | [ ]  Engineered safe sharps | [ ]  Other **specify**:       |
|  | [ ]  Aerosol management system for cell sorting |
|  |  |  |  |
| General Biosafety Laboratory Practices |
| Reference the Chapman University Biosafety Manual (BSM) |
|  | Yes | No |  |
|  | [ ]  | [ ]  | I have a current BSM that is available to staff. |
|  | [ ]  | [ ]  | I have written decontamination procedures for equipment and surfaces. |
|  | [ ]  | [ ]  | I use appropriate decontaminants with the appropriate contact time for the agents I work with. |
|  | [ ]  | [ ]  | Spills are addressed as specified in BSM. If not, written procedures are in place. |
|  | [ ]  | [ ]  | I have procedures in place for the safe use and handling of sharps that I work with. |
|  | [ ]  | [ ]  | First aid and medical follow-up procedures are in place in the event of an exposure incident.  |
|  | [ ]  | [ ]  | A biohazard label is affixed to equipment used for biological agents when appropriate. |
|  | [ ]  | [ ]  | A biohazard door sign is posted as required. Contact EH&S for assistance. |
|  | [ ]  | [ ]  | This project involves shipping of biological materials. |
|  | [ ]  | [ ]  | Biological agents are transported within building in leak-proof, secondary containers. |
|  | [ ]  | [ ]  | I have other written biosafety standard operating procedures (SOPs).If Yes, list, submit to Chapman EHS with your IBC Application packet.      |
|  | [ ]  | [ ]  | Methods used for the decontamination of biohazards waste: |
|  |  |  | [ ]  Chemical (specify):       |
|  |  |  | [ ]  Outside company for waste pick up and decontamination:       |
|  |  |  | [ ]  Other:       |
|  | [ ]  | [ ]  | This project involves specific procedures that pose an increased risk for exposure (e.g., aerosol generating procedures performed openly on the lab bench). If Yes, list:       |
|  | [ ]  | [ ]  | Biohazardous materials are transported between Chapman University buildings.If Yes, state the transportation method.       |

| Personal Protective Equipment |
| --- |
| See [the Cal/OSHA Guide](https://www.dir.ca.gov/dosh/dosh_publications/iipp.html) for applicable regulations. See the Chapman University [Chemical Hygiene Plan](http://chapman.edu/faculty-staff/risk-management/_files/environmental-health-and-safety/chapman-university-chemical-hygiene-plan.pdf) for guidance. Contact EH&S for assistance. |
|  | Yes | No |  |
|  | [ ]  | [ ]  | I have identified the PPE requirements for each proposed activity associated with this project and will enforce the use of required PPE. |
|  | [ ]  | [ ]  | Protective lab coats designed are worn while working with hazardous materials. |
|  | [ ]  | [ ]  | This project involves tasks with the potential for splash/splatter to mucous membranes. These tasks require the following PPE: |
|  |  |  | [ ]  Safety glasses | [ ]  Goggles | [ ]  Face shield |
|  |  |  | [ ]  Surgical mask | [ ]  Other (specify):       |
|  | [ ]  | [ ]  | Gloves are inspected before use and are changed when contaminated, when integrity has been compromised, and when otherwise necessary. |
|  | [ ]  | [ ]  | PPE is removed before entering non-contaminated areas (e.g., public hallways, lunch rooms). |
|  | [ ]  | [ ]  | PPE is removed in an order that minimizes cross-contamination. |
|  | List any other PPE required for your work:       |

| Training |
| --- |
|  | Yes | No |  |
|  | [ ]  | [ ]  | EH&S Biosafety LearnUpon Training is completed. Required for PIs and lab staff at a minimum of every three years. |
|  | [ ]  | [ ]  | Lab-specific biosafety training by PI/Supervisor is completed and documented. |
|  | [ ]  | [ ]  | Site-specific BBP exposure control plan training by PI/Supervisor is completed. |

Other Hazards

| Chemicals |
| --- |
| Does this project involve the following? **If Yes, please list**. Follow the Chapman University Chemical Hygiene Manual, a quick reference for safe work with hazardous chemicals. |
|  | Yes | No |  |
|  | [ ]  | [ ]  | Particularly Hazardous Substances. **Please list or attach**:       |
|  | [ ]  | [ ]  | Toxins of biological origin (e.g., TTX, Botox, Pertussis, Diphtheria). **If yes, list**:       |
|  | [ ]  | [ ]  | Nanoparticles (˂100 nm in length). **If Yes, list and specify use and/or production**:       |
|  | [ ]  | [ ]  | Controlled substances: **If yes, list**:       |
|  | [ ]  | [ ]  | Animals exposed to any of the above. **If Yes, describe**:       |
|  | [ ]  | [ ]  | Animals exposed to any of the above via drinking water or food. **If Yes, describe**:       |
|  | [ ]  | [ ]  | Anesthetic gases. **If yes, list:**       |
|  | [ ]  | [ ]  | Fixing agents: **If yes, list:**       |
|  | [ ]  | [ ]  | I have a current Laboratory Safety Manual with lab-specific chemical SOPs that is available to staff. |

| Radiation |
| --- |
| Does this project involve the following? Reference the Chapman University Radiation Safety Manual. Note: Use of radioactive materials requires prior authorization by EH&S.  |
|  | Yes | No |  |
|  | [ ]  | [ ]  | Radionuclides. Provide Radioactive Materials Authorization (RAM #):       |
|  | [ ]  | [ ]  | Radiation generating equipment. **Describe and provide location:**       |
|  | [ ]  | [ ]  | Non-ionizing radiation, including lasers, UV light and microwave sources. **Describe and provide location:**       |

|  |
| --- |
| Other Hazards |
|  | Yes | No |  |
|  | [ ]  | [ ]  | This project involves other significant hazards (e.g., climbing hazards, heavy lifting, etc.).**If Yes, explain**:       |

1. If this is a renewal, have there been any adverse incidents related to this project over the past year?

**If Yes, provide details**:

| Authorized Personnel |
| --- |
| Please list all laboratory personnel and the agents they will handle. Approval will only be given for personnel identified below, and is specific for the agents listed. Signatures are required to indicate that personnel have been informed of potential hazards, safe work practices, and that they understand and will follow approved laboratory standard operating procedures. All laboratory personnel who handle human materials or other potentially infectious material must complete annual bloodborne pathogen training. |
| **Name** | **Title (PI, PostDoc, Grad Student, Tech)** | **Agents Handled (ie cell line viral vectors)** | **Signature** | **Last Biosafety online training (Date or N/A)** | **Last Bloodborne Pathogen online training (Date or N/A)** |
|       |       |       |       |       |       |
|       |       |       |       |       |       |
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Statement of Responsibility

|  |
| --- |
| As Principal Investigator for this project, I have the responsibility to assure that my laboratory operates in a safe manner and that all staff and students are informed of risk, wear appropriate protective equipment, and are adequately trained. I will assure that all students and staff working in my laboratory receive orientation to our departmental Health & Safety Plan and departmental Emergency Plan.I understand that I am responsible for assuring that my laboratory complies with all federal, state, and local environmental laws and regulations. I will comply with shipping requirements for hazardous materials including recombinant and synthetic DNA molecules.If my work involves recombinant or synthetic DNA/RNA molecules, I acknowledge that I am responsible for full compliance with the NIH Guidelines in the conduct of recombinant and synthetic DNA/RNA research. I will neither initiate nor modify any recombinant or synthetic DNA/RNA research that requires IBC approval prior to initiation until IBC approval is given. I will report the following to an EH&S biosafety officer at 714-516-7199 or EHS@Chapman.edu as soon as possible: (1) Violations of the NIH Guidelines; (2) Biohazardous spills; (3) Loss of biohazard containment; (4) Research-related accidents; (5) Research-related illnesses; (6) Exposures or potential exposures to biohazards, including recombinant or synthetic DNA/RNA; (7) Exposures or potential exposures involving animals previously exposed to biohazards, including recombinant or synthetic DNA/RNA. If instructed I will also notify the Chapman University IBC and NIH Office of Biotechnology Activities. I will adhere to the IBC-approved emergency plans for handling accidental spills and personnel exposures.In case of incidents, I will instruct my staff to complete the [Online Accident Report](https://web.chapman.edu/incidentreporting/Login.aspx?ReturnUrl=%252fIncidentReporting%252fIncidentForm.aspx) form within 24 hours.To the best of my knowledge, the information reported on this form is correct and accurately reflects my proposed research. I further understand that I must contact EH&S Research and Occupational Safety prior to initiating any changes in my research involving biological, or recombinant or synthetic DNA/RNA materials. |
| Principal Investigator Name (printed or typed) |
|  |  |
| Principal Investigator Signature/Electronic Signature | Date |
|  | Submit your completed application and supplemental documents to EH&S, EHS@Chapman.edu |  |