**Request for Change to Biological Use Authorization**

**Required for Biological Use Authorization from the Institutional Biosafety Committee**

|  |
| --- |
| This application is for changes to existing research projects that involve biohazards and therefore require Biological Use Authorization (BUA) from the Institutional Biosafety Committee (IBC). Refer to the EH&S [Biological Research Approval](https://www.ehs.washington.edu/biological/biological-research-approval) webpage for more information about the review process.   1. Complete all questions as they apply to changes in your research project. Refer to your current BUA as you complete this form. Fields will expand as needed. Refer to the [BUA FAQs](https://www.ehs.washington.edu/biological/biological-research-approval/biological-use-authorization-bua-application-faqs) as needed. 2. Submit completed application and any supplemental documents, SOPs, or permits to EH&S Biological Safety at [ehsbio@uw.edu](mailto:ehsbio@uw.edu).   **EH&S Biological Safety ·** [**ehsbio@uw.edu**](mailto:ehsbio@uw.edu) **· Box 357165 · Phone 206-221-7770** |

**General Project Information**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Change to** BUA#     - | | | **Project Title** | | | | Check here if the title has changed | | |
| **Anticipated Start Date:** | | | [**IACUC Protocol Number**](https://www.ehs.washington.edu/biological/biological-research-approval/biological-use-authorization-bua-application-faqs#GP3)  Provide only if applicable to biohazards used in animals in this BUA application. Only one IACUC protocol can be associated with a single BUA. | | | | [**Human Subjects Division Number(s)**](https://www.ehs.washington.edu/biological/biological-research-approval/biological-use-authorization-bua-application-faqs#GP4)  Provide only if applicable to the research in this BUA application. | | |
|  | | **Name** | | **Daytime Phone** | **Preferred Email** | **UW NetID** | | **Advanced Degree(s)** | **Position**  **or Title** |
| **Principal Investigator (PI)** | |  | |  |  |  | |  |  |
| **Lab Contact**  if different than PI | |  | |  |  |  | |  |  |
| **Department** | | | | **Division** if applicable | | | | **Box Number** | |
| Yes  No | Is there a target date for funding or approval that EH&S needs to be aware of?  If yes, provide information: | | | | | | | | |
| Yes No | Do you have or need permits for this project (e.g., [USDA-APHIS](https://www.aphis.usda.gov/aphis/resources/permits), [CDC Import Permits](https://www.cdc.gov/cpr/ipp/)?  If yes, specify and submit a copy of the permit(s) with this application: | | | | | | | | |

Use this table to determine which sections of the BUA change application to complete.

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Adding…** | **Part 1** | **Part 2** | **Part 3** | **Part 4** | **Part 5** | **Part 6** | **Part 7** | **Part 8** |
| New rooms | X | X |  |  |  |  |  | X |
| New cells, cell lines, tissues, etc. | X | X | X |  |  |  |  | X |
| New wildtype microorganisms | X | X |  | X |  |  |  | X |
| New recombinant/genetically modified microorganisms | X | X |  | X | X |  |  | X |
| New recombinant/synthetic DNA/RNA, viral vectors, gene inserts | X | X |  |  | X | X |  | X |
| New gene inserts | X |  |  |  |  | X |  | X |
| New transgenic animals | X | X |  |  | X |  | X | X |
| Removing or adding personnel | No BUA change required; update with 3-year renewal. | | | | | | | |
| Changing the PI for the project | Contact EH&S at [ehsbio@uw.edu](mailto:ehsbio@uw.edu) for the next steps. | | | | | | | |

**PART ONE: Fill out this section with a description of the research changes for this BUA.**

1. Please describe the change you are requesting:

**PART TWO: Fill out this section to indicate the locations for the research in this BUA change.**

|  |  |  |  |
| --- | --- | --- | --- |
| **Facilities**  For this BUA change, list each UW research space where you will perform work with biohazardous agents. Include buildings, room numbers, biohazardous agents, activities, biosafety level, and PPE and safety equipment present. | | | |
|  | | **In Vitro Use** [FAQ](https://www.ehs.washington.edu/biological/biological-research-approval/biological-use-authorization-bua-application-faqs#CR2) | | | |
| **Building/Room** | | | **Biohazardous Agents and Activities** | **BSL, PPE, and Safety Equipment** | |
| *EXAMPLE: Life Sciences Building T287* | | | *EXAMPLE: Human cell culture and lentiviral vectors. Sequencing of P. aeruginosa.* | *EXAMPLE: BSL-2 room with biosafety cabinet. Lab coats and gloves required. Face shields are available.* | |
|  | | |  |  | |
|  | | |  |  | |
|  | | |  |  | |
|  | | |  |  | |

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Animal Use** [FAQ](https://www.ehs.washington.edu/biological/biological-research-approval/biological-use-authorization-bua-application-faqs#CR3) | | |
| **Building/Room** | | **Biohazardous Agents and Activities** | **BSL, PPE, and Safety Equipment** |
| *EXAMPLE:*  *SLU 3.1 ABSL-2 Vivarium* | | *EXAMPLE: Aerosol exposure of mice to bacteria. Injection of recDNA vaccine into mice.* | *EXAMPLE: ABSL-2 procedure rooms with biosafety cabinet. Standard DCM ABSL-2 PPE.* |
|  | |  |  |
|  | |  |  |
|  | |  |  |
|  | |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Shared Core Facilities** [FAQ](https://www.ehs.washington.edu/biological/biological-research-approval/biological-use-authorization-bua-application-faqs#CR4) (e.g., MRI, cell sorting, flow cytometry, stem cell core, UW Greenhouse) | | |
| **Facility/Building/Room** | | **Biohazardous Agents and Activities** | **BSL, PPE, and Safety Equipment** |
| *EXAMPLE:*  *Immunology Cell Analysis Facility (E386A, E386B)* | | *EXAMPLE: Cell sorting of human and non-human primate cells, imaging of mice exposed to lentiviral vectors.* | *EXAMPLE: BSL-2 microscopy and imaging room. Lab coat and gloves worn.* |
|  | |  |  |
|  | |  |  |
|  | |  |  |
|  | |  |  |
| If additional spaces are needed, complete and submit the [BUA Facilities Supplemental](https://www.ehs.washington.edu/system/files/resources/bua-rooms.docx). | | | |

**PART THREE: Fill out this section if adding new biological source materials such as tissues, cells, cell lines, body fluids, induced pluripotent stem cells, etc.**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Tissue, Blood, and Body Fluids**  Does this BUA change involve tissue, blood, or body fluids? List name or type. | | | | | |
|  | Yes | | No | |  |
|  |  | |  | | Human: |
|  |  | |  | | Non-human primate: |
|  |  | |  | | Other animals: |
|  |  | |  | | Are tissues or cells administered to animals or transplanted between species? Describe and include species: |
| **Culture of Primary Cells or Cell Lines**  Does this BUA change involve primary cells or cell lines? List name or type of cell lines. [FAQ](https://www.ehs.washington.edu/biological/biological-research-approval/biological-use-authorization-bua-application-faqs#CC1) | | | | | |
|  | Yes | | No | |  |
|  |  | |  | | Human: |
|  |  | |  | | Use of human embryonic stem cells (hESCs)? [ESCRO](https://www.washington.edu/research/embryonic-stem-cell-research-oversight-escro/) review required. |
|  |  | |  | | Non-human primate: |
|  |  | |  | | Other animals (e.g., mice, canines, zebrafish): |
| **Creation or Use of Induced Pluripotent Stem Cells (iPSCs)**  Does this BUA change involve the use or generation of induced pluripotent stem cells (iPSCs)? (Research with iPSCs may require [ESCRO](https://www.washington.edu/research/embryonic-stem-cell-research-oversight-escro/) review and approval.) [FAQ](https://www.ehs.washington.edu/biological/biological-research-approval/biological-use-authorization-bua-application-faqs#CC2) | | | | | |
|  | Yes | | No | |  |
|  |  | |  | | Use of induced pluripotent stem cells (iPSCs)? List species of cells and the method(s) and reprogramming factors used to create each iPS cell line (e.g., human iPSCs made with Sendai viral vector with Yamanaka factors): |
|  |  | |  | | Generation of iPSCs? List the species of cells and method(s) and reprogramming factors that will be used to generate iPSCs (e.g., murine iPSCs made with plasmids expressing Thomson factors): |
|  |  | |  | | If iPSCs were made with viral vectors, have they been tested and shown to be free of replication competent virus (RCV)? If tested, submit results to EH&S with this application. |
|  |  | |  | | Use of iPSCs in animals? If yes, specify which iPSCs and which species of animal: |
| **Bloodborne Pathogens (BBP)** [FAQ](https://www.ehs.washington.edu/biological/biological-research-approval/biological-use-authorization-bua-application-faqs#BBP1) | | | | | | |
|  | | Yes | | No |  | |
|  | |  | |  | Does this project involve work with bloodborne pathogens or 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](http://www.ehs.washington.edu/biological/bloodborne-pathogens-bbp-program))? If yes, the [Washington State Bloodborne Pathogens (BBP) Rule](http://app.leg.wa.gov/wac/default.aspx?Cite=296-823) applies. [BBP program](http://www.ehs.washington.edu/biological/bloodborne-pathogens-bbp-program) requirements include completion of the following:   1. Annual [Bloodborne Pathogens for Researchers Training](https://www.ehs.washington.edu/training/bloodborne-pathogens-researchers-online) 2. [Site-specific BBP Exposure Control Plan](http://www.ehs.washington.edu/system/files/resources/bbpecp.docx): Submit with this application. | |

**PART FOUR: Fill out this section if adding new microorganisms including bacteria, viruses, yeasts, fungi, parasites, or prions.**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Wildtype Microorganisms** (Bacteria, Viruses, Yeasts, Fungi, Parasites, and Prions) | | | | | | |
| 1. **Wildtype Microorganism Table** [FAQ](https://www.ehs.washington.edu/biological/biological-research-approval/biological-use-authorization-bua-application-faqs#WM1) | | | | | | |
|  | Yes | No | |  | | |
|  |  |  | | Will wildtype/non-genetically modified microorganisms be used? If yes, complete the table below with the wildtype microorganisms that you use in this project. If you need additional space, fill out the [Wildtype Microorganism Supplemental](https://www.ehs.washington.edu/system/files/resources/bua-wildtype.docx). If not using wildtype microorganisms, continue to the next applicable section. | | |
| 1. **Genus and species.** Include strain information that may impact risk assessment within species. | | | | | 1. [**Risk Group (RG)**](https://my.absa.org/tiki-index.php?page=Riskgroups) **1, 2 or 3** | 1. **Administered to animals or plants?** If yes, specify species and method of administration. | |
| *EXAMPLE: Vaccinia virus, NYCBH strain* | | | | | *EXAMPLE: RG 2* | *EXAMPLE: IP injection to mice and rats* | |
|  | | | | | RG | Yes. Describe:  No | |
|  | | | | | RG | Yes. Describe:  No | |
|  | | | | | RG | Yes. Describe:  No | |
|  | | | | | RG | Yes. Describe:  No | |
|  | | | | | RG | Yes. Describe:  No | |
|  | | | | | RG | Yes. Describe:  No | |
|  | | | | | RG | Yes. Describe:  No | |
|  | | | | | RG | Yes. Describe:  No | |
|  | | | | | RG | Yes. Describe:  No | |
|  | | | | | RG | Yes. Describe:  No | |
|  | | | | | RG | Yes. Describe:  No | |
|  | | | | | RG | Yes. Describe:  No | |
|  | Yes | No |  | | | | | |
|  |  |  | Are any of the wildtype microorganisms listed above resistant to frontline therapeutics or would require specialized treatment if infection occurred? Include naturally resistant organisms and clinical strains. If yes, list and describe: | | | | |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Recombinant Microorganisms** (Bacteria, Viruses, Yeasts, Fungi, Parasites, and Prions) | | | | | | | | | | | | | |
| 1. **Recombinant Microorganism Table** [FAQ](https://www.ehs.washington.edu/biological/biological-research-approval/biological-use-authorization-bua-application-faqs#RM1) | | | | | | | | | | | | | |
|  | Yes | No | |  | | | | | | | | | |
|  |  |  | | Will recombinant or genetically modified microorganisms be used or created? If yes, complete the table below. List recombinant or genetically modified organisms that you will use or that you will create. If you need additional space, fill out the [Recombinant Microorganism Supplemental](https://www.ehs.washington.edu/system/files/resources/bua-recombinant.docx). If not using recombinant microorganisms, continue to the next applicable section. | | | | | | | | | |
| 1. **Genus and species.** Include strain information that may impact risk assessment within species. | | | | | | | | 1. [**Risk Group (RG)**](https://my.absa.org/tiki-index.php?page=Riskgroups) **1, 2 or 3** | | 1. **Describe the genetic modifications** that you propose to make or that have already been made. | 1. **Administered to animals or plants?** If yes, specify species and method of administration. | | |
| *EXAMPLE: Pseudomonas aeruginosa GFP (ATCC 15692)* | | | | | | | | *EXAMPLE:*  *RG 2* | | *EXAMPLE: Expresses GFP under control of P-lac promoter (E. coli)* | *EXAMPLE: IP and footpad injection to mice* | | |
|  | | | | | | | | RG | |  | Yes. Describe:  No | | |
|  | | | | | | | | RG | |  | Yes. Describe:  No | | |
|  | | | | | | | | RG | |  | Yes. Describe:  No | | |
|  | | | | | | | | RG | |  | Yes. Describe:  No | | |
|  | | | | | | | | RG | |  | Yes. Describe:  No | | |
|  | | | | | | | | RG | |  | Yes. Describe:  No | | |
|  | | | | | | | | RG | |  | Yes. Describe:  No | | |
|  | | | | | | | | RG | |  | Yes. Describe:  No | | |
|  | | | | | | | | RG | |  | Yes. Describe:  No | | |
|  | | | | | | | | RG | |  | Yes. Describe:  No | | |
|  | | | | | | | | RG | |  | Yes. Describe:  No | | |
|  | Yes | No |  | | | | | | | | | | |
|  |  |  | Will antibiotic resistance be conferred to any of the microorganisms listed above? If yes, list species and antibiotic resistance: | | | | | | | | | |
|  |  |  | Are any of the recombinant microorganisms listed above resistant to antibiotics, antivirals, antifungals, or frontline therapeutics? Refer to the [Sanford Guide](https://www.offcampus.lib.washington.edu/login?url=https://webedition.sanfordguide.com/) (UW log-in required to access) If yes, list and describe: | | | | | | | | | |
|  |  |  | Will any of the genetic changes listed above alter the virulence or tropism of the organism? If yes, describe: | | | | | | | | | |
|  |  |  | Is there potential for any recombinant infectious agents listed above to be released or shed from cells, animals, or plants? If yes, explain. [FAQ](https://www.ehs.washington.edu/biological/biological-research-approval/biological-use-authorization-bua-application-faqs#RM2) | | | | | | | | | |
| **Select Agents**  The [Federal Select Agent Program (FSAP)](https://www.selectagents.gov/) oversees the possession, use and transfer of biological select agents and toxins that have the potential to pose a severe threat to public health or to animal or plant products. | | | | | | | | | | | | |
| 1. **Select Agent Table** | | | | | | | | | | | | |
|  | Yes | No |  | | | | | | | | | |
|  |  |  | Will this project involve any [Select Agents](https://www.selectagents.gov/sat/list.htm), **including** [[**ex**](https://www.selectagents.gov/sat/exclusions/index.htm)**cluded**](https://www.selectagents.gov/sat/exclusions/index.htm) **or attenuated strains**? [FAQ](https://www.ehs.washington.edu/biological/biological-research-approval/biological-use-authorization-bua-application-faqs#SA1)  If yes, complete the table below. If not, continue to the next applicable section. | | | | | | | | | |
| 1. **Select Agent:**   Genus, species, strain name (if applicable). | | | | | | | 1. **Excluded?**   Is it excluded from FSAP regulations? | | 1. **Strain Information:**   Describe the strain and/or any genetic modifications made to this agent. If excluded or attenuated, include the rationale for why the agent is excluded. | | | 1. **Source:**   List the source and form of the select agent. |
| *EXAMPLE: Ebola virus strain ΔVP30* | | | | | | | *EXAMPLE:*  *Yes  No* | | *EXAMPLE: ΔVP30 is excluded as it lacks the gene encoding for the VP30 protein so it is replication incompetent and cannot form infectious progeny* | | | *EXAMPLE: cDNA clone from collaborators at Georgina University* |
|  | | | | | | | Yes  No | |  | | |  |
|  | | | | | | | Yes  No | |  | | |  |
|  | | | | | | | Yes  No | |  | | |  |
|  | | | | | | | Yes  No | |  | | |  |
|  | | | | | | | Yes  No | |  | | |  |
|  |  | | | | | |  | |  | | |  |
|  | Yes | No |  | | | | | | | | | |
|  |  |  | Are you working with any of the subset of select agents or toxins that are subject to [Dual Use Research of Concern (DURC)](https://www.ehs.washington.edu/biological/select-agent-program/dual-use-research-concern-durc)? Describe: | | | | | | | | | |
|  |  |  | Will you be conducting any of the following types of experiments involving select agent microorganisms, chimeric viruses, or nucleic acids from select agents? [FAQ](https://www.ehs.washington.edu/biological/biological-research-approval/biological-use-authorization-bua-application-faqs#SA2) | | | | | | | | | |
|  |  |  | Yes | | No |  | | | | | | |
|  |  | a. |  | |  | [Positive strand RNA forms of select agent complete viral genomes](https://www.selectagents.gov/compliance/guidance/nucleic/regulated.htm) that can be translated into protein precursors for virus production. Describe: | | | | | | |
|  |  | b. |  | |  | Genetic or other modifications of an [excluded select agent strain](https://www.selectagents.gov/sat/exclusions/index.htm) that could modify the attenuation such that virulence or toxic activity is restored or enhanced?  Describe: | | | | | | |
|  |  | c. |  | |  | Creating or working with chimeric viruses whose genomes contain the backbone and replication machinery of a select agent virus or contain genes from different select agent viruses? Describe: | | | | | | |
|  |  | d. |  | |  | Creating or working with chimeras composed of select agents and non-select agents from the same virus family? Describe: | | | | | | |
|  | Will you be conducting any of the following types of experiments involving select toxins? | | | | | | | | | | | |
|  |  |  | Yes | | No |  | | | | | | |
|  |  | a. |  | |  | Work with select toxins including in [permissible amounts](https://www.selectagents.gov/sat/permissible.htm)? Describe: | | | | | | |
|  |  | b. |  | |  | Recombinant or synthetic nucleic acids encoding for the toxic form(s) of regulated select toxins? Describe: | | | | | | |

**PART FIVE: Fill out this section to add any new recombinant or synthetic nucleic acid work (including recombinant microorganisms or viral vectors) or to add new transgenic animals.**

|  |  |  |  |
| --- | --- | --- | --- |
| **Recombinant and Synthetic DNA and RNA (rDNA)** [FAQ](https://www.ehs.washington.edu/biological/biological-research-approval/biological-use-authorization-bua-application-faqs" \l "DNA1)  For each question, check if you will perform the experiments in this project and describe when applicable. | | | |
|  | Yes | No |  |
|  |  |  | Does this project include the use of any form of recombinant or synthetic DNA/RNA (rDNA)? Refer to the [NIH Guidelines](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.htm) and [EH&S Experiments Covered by the NIH Guidelines](https://www.ehs.washington.edu/system/files/resources/experiments-NIH-guidelines.pdf) for more information. If yes, complete questions below. If no, proceed to the next applicable section. |
|  | **Section III-F (Experiments exempt from the NIH Guidelines)** | | |
|  | Yes | No |  |
|  |  |  | 1. rDNA that is not in organisms or viruses, such as rDNA used in PCR, probes or primers, or DNA/RNA sequencing? |
|  |  |  | 1. Use of rDNA in microorganisms that are exempt under Section III-F and [Appendix C](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.htm) of the NIH Guidelines (e.g., E. coli K-12, S. cerevisiae, B. subtilis)? Describe: |
|  |  |  | 1. Use of transgenic rodents requiring ABSL-1? |
|  | **Section III-E (Experiments that require IBC notice simultaneous with initiation)** | | |
|  | Yes | No |  |
|  |  |  | 1. rDNA with liposome complex, nanoparticles or other modifications that render them capable of penetrating cellular membranes? Describe: |
|  |  |  | 1. rDNA molecules containing no more than two-thirds of the genome of any eukaryotic virus propagated or maintained in cells or tissue culture? Describe: |
|  |  |  | 1. Creation of transgenic rodents requiring ABSL-1? Describe: |
|  |  |  | 1. Use of [E. coli strains](https://blink.ucsd.edu/safety/research-lab/biosafety/nih/e-coli.html) other than K-12 for cloning/protein expression. Describe: |
|  | **Section III-D (Experiments that require IBC approval prior to initiation)** | | |
|  | Yes | No |  |
|  |  |  | 1. rDNA modified pathogenic microorganisms (Risk Group 2 and higher)? If yes, complete the table in Question 20. Describe: |
|  |  |  | 1. Nucleic acids from Risk Group 3 or 4 agents cloned into prokaryotes or lower eukaryotes including E. coli K-12 or other exempt microorganisms? Describe: |
|  |  |  | 1. Viral vectors for gene transfer and/or use of cell lines transduced with viral vectors? If yes, complete table in Question 39 and describe: |
|  |  |  | 1. Plasmid containing an entire viral genome or an infectious clone. Describe: |
|  |  |  | 1. Administration of rDNA to animals, including transfected transduced cells, mRNA, plasmids, and/or any genetically modified microorganism? Describe: |
|  |  |  | 1. Creation/breeding/use of transgenic animals other than rodents, including invertebrates?   List species: |
|  |  |  | 1. Large-scale culture (>10 L single vessel) of any recombinant microorganisms? Describe: |
|  |  |  | 1. Use or creation of recombinant influenza viruses? If yes, complete the [Influenza Virus Supplemental Form](https://www.ehs.washington.edu/system/files/resources/bua-influenza.docx) and attach it to your BUA application submission. [FAQ](https://www.ehs.washington.edu/biological/biological-research-approval/biological-use-authorization-bua-application-faqs#DNA2) |
|  |  |  | 1. Development of gene-drive modified organisms (GDMOs)? Or will transgenes or combinations of transgenes result in the preferential inheritance of recombinant DNA? Refer to the [NIH GDMO reference](https://osp.od.nih.gov/wp-content/uploads/2024/03/gdmo-reference.pdf). Describe: |
|  | **Section III-C (Experiments that require IBC and IRB approval before enrolling participants)** | | |
|  | Yes | No |  |
|  |  |  | Human gene transfer or administration of any rDNA to humans? If yes, STOP and submit [Clinical Trial BUA application](https://www.ehs.washington.edu/biological/clinical-trials). |
|  | **Section III-B (Experiments that require NIH and IBC approval prior to initiation)** Refer to [NIH FAQs on toxin experiments](https://osp.od.nih.gov/policies/biosafety-and-biosecurity-policy/faqs-on-toxin-experiments/). | | |
|  | Yes | No |  |
|  |  |  | Cloning of toxin molecules with a LD50 less than 100 ng/kg? Describe: |
|  | **Section III-A (Experiments that require NIH Director and IBC approval prior to initiation)** | | |
|  | Yes | No |  |
|  |  |  | Deliberate transfer of drug resistance to a microorganism that is not known to acquire it naturally and that could compromise treatment or control? Describe: |
| **Recombinant or Synthetic DNA/RNA Activities**  Will this project include any of the following: | | | |
|  | Yes | No |  |
|  |  |  | Use of gene editing technologies (e.g., CRISPR/Cas9)? Describe construct, delivery method, and gene targets: |
|  |  |  | Environmental release or field testing of genetically engineered organisms? Describe: |
|  |  |  | Experiments involving genes coding for toxin molecules with an LD50 of <100 micrograms per kilograms and >100 nanograms per kilograms body weight? If so, registration with NIH is required prior to initiating the experiments. Refer to [NIH Guidelines](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.htm) Appendix F.  Describe: |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Viral Vector and Gene Delivery Methods Table** [FAQ](https://www.ehs.washington.edu/biological/biological-research-approval/biological-use-authorization-bua-application-faqs#GD1)  List all [viral vectors](https://www.ehs.washington.edu/biological/viral-vectors-gene-transfer), gene delivery methods, transduced or transfected cells, and other forms or recombinant or synthetic nucleic acids in the table below. If additional spaces are needed, complete and submit the [Viral Vector and Gene Delivery Methods Supplemental](https://www.ehs.washington.edu/system/files/resources/bua-genedelivery.docx). For large numbers of genes, attach a complete list of genes. For large numbers of genes not yet identified, complete question 42. | | | | | |
|  | |  |  |  |  |  |
| **Viral Vector System, Gene Delivery Method, or Transduced or Transfected Cells:** Choose system and describe as needed. | | **Replication Status:** Choose [replication status](https://www.ehs.washington.edu/biological/biological-research-approval/biological-use-authorization-bua-application-faqs#GD2) and describe if needed. If RCV tested, submit results. | **Transgenes:** List[gene inserts](https://www.ehs.washington.edu/biological/biological-research-approval/biological-use-authorization-bua-application-faqs#GD3) to be overexpressed or knocked down. Use [RefSeq](http://www.ncbi.nlm.nih.gov/refseq/rsg/) gene names. | [**In vitro**](https://www.ehs.washington.edu/biological/biological-research-approval/biological-use-authorization-bua-application-faqs#GD4) **use: Will the vector system be used with cells?**  Specify cell species/type and activities as applicable. | [**In vivo**](https://www.ehs.washington.edu/biological/biological-research-approval/biological-use-authorization-bua-application-faqs#GD5) **use: Will the vector or modified cells be administered to an animal?** If so, specify animal species, method of administration, and exactly what will be administered to the animal. | **Is this created in your lab?** |
| *EXAMPLE: Other (explain): mRNA in nanolipid carrier* | | *EXAMPLE: Not applicable (non-viral)* | *EXAMPLE: GFP, RFP, T cell Receptors* | *EXAMPLE: Human PBMCs will be transduced to encode the T cell receptors* | *EXAMPLE: Human cells transfected with DNA implanted into mice footpads* | *(No description needed.)* |
| Click here to select.  Describe if needed: | | Click here to select.  Describe if needed: |  | Yes:  No | Yes:  No | Yes  No |
| Click here to select.  Describe if needed: | | Click here to select.  Describe if needed: |  | Yes:  No | Yes:  No | Yes  No |
| Click here to select.  Describe if needed: | | Click here to select.  Describe if needed: |  | Yes:  No | Yes:  No | Yes  No |
| Click here to select.  Describe if needed: | | Click here to select.  Describe if needed: |  | Yes:  No | Yes:  No | Yes  No |
| Click here to select.  Describe if needed: | | Click here to select.  Describe if needed: |  | Yes:  No | Yes:  No | Yes  No |
| Click here to select.  Describe if needed: | | Click here to select.  Describe if needed: |  | Yes:  No | Yes:  No | Yes  No |
| Click here to select.  Describe if needed: | | Click here to select.  Describe if needed: |  | Yes:  No | Yes:  No | Yes  No |
| Click here to select.  Describe if needed: | | Click here to select.  Describe if needed: |  | Yes:  No | Yes:  No | Yes  No |
| Click here to select.  Describe if needed: | | Click here to select.  Describe if needed: |  | Yes:  No | Yes:  No | Yes  No |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Replication Competent Viral Vectors and Transduced Cells** | | | | |
|  | Yes | No | N/A |  |
|  |  |  |  | Is there potential for release or shedding of replication competent viral vectors from exposed cells, animals, or plants? [FAQ](https://www.ehs.washington.edu/biological/biological-research-approval/biological-use-authorization-bua-application-faqs#GD6) Describe: |
| **Third Generation Lentiviral Vectors**  Refer to [Third Generation Lentiviral Vectors](http://www.ehs.washington.edu/system/files/resources/third-gen-lenti.pdf) for more information. [FAQ](https://www.ehs.washington.edu/biological/biological-research-approval/biological-use-authorization-bua-application-faqs#GD7) | | | | |
| 1. 50. |  |  |  | If using third generation lentiviral vectors, list all four plasmids and provide information or link to Addgene if available. Refer to [Addgene Lentivirus Guide](https://www.addgene.org/guides/lentivirus/).   1. Packaging plasmid 1 (gag/pol): 2. Packaging plasmid 2 (rev): 3. Transfer plasmid: 4. Envelope plasmid: |
|  | | | | |

**PART SIX: Fill out this section if adding any new gene inserts.**

|  |  |  |  |
| --- | --- | --- | --- |
| **Gene Inserts** | | | |
|  | For research involving a large number of genes not yet identified, list the categories or general functions of the genes. [FAQ](https://www.ehs.washington.edu/biological/biological-research-approval/biological-use-authorization-bua-application-faqs#GI1) | | |
|  |  |  |  |
| **Oncogenes and Tumor Suppressor Genes** [FAQ](https://www.ehs.washington.edu/biological/biological-research-approval/biological-use-authorization-bua-application-faqs#OG1) | | | |
|  | Yes | No |  |
|  |  |  | Do any of your proposed genes appear in the following databases? Use common [RefSeq](http://www.ncbi.nlm.nih.gov/refseq/rsg/) gene names. If yes, they are likely oncogenes or tumor suppressors.   1. [*Cancer Gene Census*](http://cancer.sanger.ac.uk/cosmic/census/tables?name=symbol) List: 2. [*Cancer Genetics Web*](http://www.cancer-genetics.org/genes_a.htm) List: |
|  |  |  | Are any of your proposed genes well described in the scientific literature as oncogenes or tumor suppressors? If yes, list genes, describe and cite sources. |
|  |  |  | Do you have other reasons to believe that your proposed genes are oncogenes or tumor suppressors? If yes, list genes and describe. |
|  |  |  | If yes to any of the four preceding questions, are you overexpressing or dysregulating oncogenes or knocking down or silencing tumor suppressors? The IBC will consider this when setting biocontainment for this work. [FAQ](https://www.ehs.washington.edu/biological/biological-research-approval/biological-use-authorization-bua-application-faqs#OG2) If yes, describe: |

**PART SEVEN: Fill out this section if adding any new recombinant or synthetic nucleic acid work (including recombinant microorganisms or viral vectors) or if adding new non-rodent transgenic animal species.**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Transgenic Animals** If this project involves the creation, breeding, or use of genetically modified animals, complete the table below. Note: Transgenic animals include vertebrates and invertebrates such as *Drosophila*, mosquitoes, fish, *Caenorhabditis elegans*, oysters, frogs, mice, rats, and pigs. [FAQ](https://www.ehs.washington.edu/biological/biological-research-approval/biological-use-authorization-bua-application-faqs#TA1) | | | | | | |
|  | Yes | No |  | | | |
|  |  |  | Are you using, creating, or breeding any transgenic animals? | | | |
| 1. **List species of transgenic animals.** | | | | **Species:** | **Species:** | **Species:** |
| 1. **List all strains for each species.** | | | |  |  |  |
| 1. **Are you creating transgenic animals?** | | | | Yes  No  Specify method: | Yes  No  Specify method: | Yes  No  Specify method: |
| 1. **Are you generating transgenic rodents through the Dept. of Comparative Medicine?** | | | | Yes  No  Specify location: | Yes  No  Specify location: | Yes  No  Specify location: |
| 1. **Are you breeding transgenic animals?**   **If yes, select all that apply.** | | | | Yes  No  Breeding of rodents that have a gene encoding more than fifty percent of an exogenous eukaryotic virus  Breeding of rodents in which the transgene is under the control of a gammaretroviral long terminal repeat (LTR) | Yes  No  Breeding of rodents that have a gene encoding more than fifty percent of an exogenous eukaryotic virus  Breeding of rodents in which the transgene is under the control of a gammaretroviral long terminal repeat (LTR) | Yes  No  Breeding of rodents that have a gene encoding more than fifty percent of an exogenous eukaryotic virus  Breeding of rodents in which the transgene is under the control of a gammaretroviral long terminal repeat (LTR) |
| 1. **Will transgenic animals generated or used have the potential to produce or release toxic or infectious products?** | | | | Yes  No  If yes, describe: | Yes  No  If yes, describe: | Yes  No  If yes, describe: |

**PART EIGHT: Complete and sign for all submissions.**

|  |  |  |
| --- | --- | --- |
| Principal Investigator Statement of Responsibility [FAQ](https://www.ehs.washington.edu/biological/biological-research-approval/biological-use-authorization-bua-application-faqs#SR1)  **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 Biological Safety prior to initiating any changes in my research involving biological materials (including recombinant or synthetic DNA/RNA).**    Principal Investigator Name (printed or typed)    Principal Investigator Signature/Electronic Signature Date | | |
|  | Submit completed application and any supplemental documents, SOPs or permits to EH&S Biological Safety at [ehsbio@uw.edu](mailto:ehsbio@uw.edu) or by responding to your BUA renewal request email. |  | |
|  | **EH&S Biological Safety ·** [**ehsbio@uw.edu**](mailto:ehsbio@uw.edu) **· Box 357165 · 206-221-7770** |  | |