**Request for Change to Biological Use Authorization**

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

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| This application is for changes to research projects that involve biohazards and therefore require Biological Use Authorization (BUA) from the Institutional Biosafety Committee (IBC). More information about this application and the review process is available on the [EH&S website](https://www.ehs.washington.edu/biological/biological-research-approval).1. Complete all questions of this Request for Change to BUA as they apply to changes in your research project. Refer to your current BUA as you complete this form. Fields will expand as needed.
2. Submit your completed application and supplemental documents to EH&S Research and Occupational Safety. Incomplete applications may be returned to you. Electronic submissions are preferred.

**EH&S Research and Occupational Safety****ehsbio@uw.edu** **· box 357165 · phone 206.221.7770 · fax 206.221.3068** |

**General Project Information**

[See FAQ](http://www.ehs.washington.edu/biological-use-authorization-bua-application-faqs)

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| **Change to**  BUA#     -    | **Project Title**       |
|  | **Name** | **Phone** | **Email** | **UW NetID** |
| **Principal Investigator** |  |    .   .     |  |  |
| **Lab Contact** if different than PI |  |    .   .     |  |  |
| [**IACUC Protocol Number**](http://www.ehs.washington.edu/biological-use-authorization-bua-application-faqs#GP3)     -   | **Anticipated Start Date:**       |
| **[ ]** Yes**[ ]** No | Do you have/need permits for this project (e.g., [USDA-APHIS](https://www.aphis.usda.gov/aphis/resources/permits), [CDC](https://www.cdc.gov/cpr/ipp/))? If yes, specify and submit permit with this application:       |

**Research Change Description**

1. Please describe the change you are requesting. [See FAQ.](http://www.ehs.washington.edu/rbsresplan/faqs.shtm#researchdescriptionq2)

If you need help deciding which sections of this form you should fill out, please use this table.

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| Adding… | Part 1 | Part 2 | Part 3 | Part 4 | Part 5 | Part 6 | Part 7 | Part 8 | Part 9 |
| New rooms | x |  |  |  |  |  |  |  |  |
| New agents | x |  | x |  |  |  |  |  |  |
| New recombinant microorganisms | x |  | x | x |  |  |  |  | x |
| Human or non-human primate blood, tissue, cells, etc. | x | x |  |  |  |  |  |  |  |
| New gene delivery methods | x |  |  |  |  | x | x | x | x |
| New gene inserts | x |  |  |  |  | x | x | x | x |
| Removing or adding personnel | No need to submit this form. Personnel are collected only at the 3-year renewal. |
| Changing the project PI | Contact EH&S at ehsbio@uw.edu for the next steps. |

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| **PART ONE.** **Facilities**List each UW research space where you will perform work with biohazardous agents. Identify specific buildings, rooms, and activities. |
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|  | ***In vitro* Use** |
| **Building/Room** | **Activities** | **Biohazardous Agents** | **Comments** |
| *Health Sciences Building, T287***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.* |
|       |       |       |       |
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|  | **Animal Use**  |
| **Building/Room** | **Activities** | **Biohazardous Agents** | **Comments** |
| *Health Sciences Building, T287***EXAMPLE** | *(e.g., implanting human cells in mice, perfusions of mice exposed to reovirus, 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.* |
|       |       |       |       |
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|  | **Shared Core Facilities** (e.g., MRI, FACS, hESC, UW Botany Greenhouse) |
| **Facility/Building/Room** | **Activities** | **Biohazardous Agents** | **Comments** |
| *MRI / Brotman B67***EXAMPLE** | *(e.g., cell sorting, imaging of animals, flow cytometry)* | *(e.g., cell lines, animal cells from exposed animals, cells with recombinant DNA)* |  |
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| If additional spaces are needed, complete and submit the [Additional Facilities Table](http://www.ehs.washington.edu/system/files/resources/addroom.docx). |

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| **PART TWOTissue, Blood, Body Fluids, and Cells** [See FAQs.](http://www.ehs.washington.edu/biological-use-authorization-bua-application-faqs#CC1)List type and source. |
|  | Yes | No |  |
|  | [ ]  | [ ]  | Human:       |
|  |  |  | Yes | No |  |
|  |  | a. | [ ]  | [ ]  | Human embryonic stem cells (hESCs) |
|  |  | b. | [ ]  | [ ]  | Use of human induced pluripotent stem cells (iPSCs). |
|  |  | c. | [ ]  | [ ]  | Generation of human induced pluripotent stem cells (iPSCs). If yes, describe the method used:      If yes to b or c, complete parts four and six. |
|  | [ ]  | [ ]  | Non-human primate:       |
|  | [ ]  | [ ]  | Other animals:       |
|  | [ ]  | [ ]  | Are tissues or cells transplanted between species? If yes, describe:       |
| **Bloodborne Pathogens** [See FAQs.](http://www.ehs.washington.edu/biological-use-authorization-bua-application-faqs#bbp1) |
|  | Yes | No |  |
|  | [ ]  | [ ]  | This change involves new research 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). See [list of 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.**
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| **PART THREE Fill out this section if you are adding any new bacteria, viruses, yeasts, fungi, parasites, and/or prions.** |
| 1. **Microorganism Table** [See FAQs.](https://www.ehs.washington.edu/biological-use-authorization-bua-application-faqs#MG1)
 |
| **a.** **Genus & Species** | **b.**[**Risk Group**](https://my.absa.org/tiki-index.php?page=Riskgroups) | **c.****Recombinant?** | **d.** **Administered to cells? (specify species)** | **e.****Administered to animals? (specify species)** |
| *Pseudomonas aeruginosa***EXAMPLE**  | *[ ]  Risk Group 1**[x]  Risk Group 2**[ ]  Risk Group 3* | *[x]  yes [ ]  no* | *[x]  yes: human cells**[ ]  no* | *[x]  yes, wild type: mice* *[ ]  yes, transgenic:**[ ]  no* |
|       | [ ]  Risk Group 1[ ]  Risk Group 2[ ]  Risk Group 3 | [ ]  yes [ ]  no | [ ]  yes:      [ ]  no | [ ]  yes, wild type:      [ ]  yes, transgenic:      [ ]  no |
|       | [ ]  Risk Group 1[ ]  Risk Group 2[ ]  Risk Group 3 | [ ]  yes [ ]  no | [ ]  yes:      [ ]  no | [ ]  yes, wild type:      [ ]  yes, transgenic:      [ ]  no |
|       | [ ]  Risk Group 1[ ]  Risk Group 2[ ]  Risk Group 3 | [ ]  yes [ ]  no | [ ]  yes:      [ ]  no | [ ]  yes, wild type:      [ ]  yes, transgenic:      [ ]  no |
|       | [ ]  Risk Group 1[ ]  Risk Group 2[ ]  Risk Group 3 | [ ]  yes [ ]  no | [ ]  yes:      [ ]  no | [ ]  yes, wild type:      [ ]  yes, transgenic:      [ ]  no |
|       | [ ]  Risk Group 1[ ]  Risk Group 2[ ]  Risk Group 3 | [ ]  yes [ ]  no | [ ]  yes:      [ ]  no | [ ]  yes, wild type:      [ ]  yes, transgenic:      [ ]  no |
|       | [ ]  Risk Group 1[ ]  Risk Group 2[ ]  Risk Group 3 | [ ]  yes [ ]  no | [ ]  yes:      [ ]  no | [ ]  yes, wild type:      [ ]  yes, transgenic:      [ ]  no |
|       | [ ]  Risk Group 1[ ]  Risk Group 2[ ]  Risk Group 3 | [ ]  yes [ ]  no | [ ]  yes:      [ ]  no | [ ]  yes, wild type:      [ ]  yes, transgenic:      [ ]  no |
|       | [ ]  Risk Group 1[ ]  Risk Group 2[ ]  Risk Group 3 | [ ]  yes [ ]  no | [ ]  yes:      [ ]  no | [ ]  yes, wild type:      [ ]  yes, transgenic:      [ ]  no |
|       | [ ]  Risk Group 1[ ]  Risk Group 2[ ]  Risk Group 3 | [ ]  yes [ ]  no | [ ]  yes:      [ ]  no | [ ]  yes, wild type:      [ ]  yes, transgenic:      [ ]  no |
|       | [ ]  Risk Group 1[ ]  Risk Group 2[ ]  Risk Group 3 | [ ]  yes [ ]  no | [ ]  yes:      [ ]  no | [ ]  yes, wild type:      [ ]  yes, transgenic:      [ ]  no |

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| **Hazard Identification****PART FOUR Complete if you are adding any new recombinant or synthetic DNA/RNA work (such as recombinant bacteria or viral vectors) or if you are adding a new transgenic species other than rodents.****Recombinant and Synthetic DNA and RNA** [See FAQs.](http://www.ehs.washington.edu/biological-use-authorization-bua-application-faqs#DNA1) |
|  | Yes | No |  |
|  | [ ]  | [ ]  | This project **change** includes the **new** use of any form of recombinant or synthetic DNA or RNA. |
| Does this project change involve the following? |
|  | [ ]  | [ ]  | Construction and/or use of synthetic DNA/RNA (e.g., probes, DNA or RNA oligonucleotides, base-pair analogs).  |
|  | [ ]  | [ ]  | Creation of c-DNA/genomic libraries.  |
|  | [ ]  | [ ]  | DNA/RNA sequencing. |
|  | [ ]  | [ ]  | Use of recombinant or synthetic DNA/RNA in microorganisms. If yes, list genus, species and strains (e.g., lentiviral vectors, agrobacterium). [See FAQ.](http://www.ehs.washington.edu/biological-use-authorization-bua-application-faqs#DNA2)       |
|  | [ ]  | [ ]  | Use of recombinant or synthetic DNA/RNA in animals (somatic cells or germ-line transgenics) including insects, nematodes, and mammals. If yes, describe and list species. [See FAQ.](http://www.ehs.washington.edu/biological-use-authorization-bua-application-faqs#DNA3)       |
|  | [ ]  | [ ]  | Use of recombinant or synthetic DNA/RNA in plants (somatic cells or germ-line transgenics). If yes, describe.       |
|  | [ ]  | [ ]  | Use of recombinant or synthetic DNA/RNA in cell culture. If yes, describe and list species.       |
|  | [ ]  | [ ]  | 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.       |
|  | [ ]  | [ ]  | Potential for infectious agents to be produced/released from recombinant cells, animals, or plants. If yes, explain. [See FAQ.](http://www.ehs.washington.edu/biological-use-authorization-bua-application-faqs#DNA4)       |
|  | [ ]  | [ ]  | Environmental release or field testing of genetically engineered organisms. If yes, explain.       |
|  | This project change includes research with recombinant or synthetic DNA/RNA using the following gene delivery techniques (covered under section III-E of the NIH Guidelines): |
|  | [ ]  Liposome complex | [ ]  Nanomaterial (<100 nm in length) |

 **PART FIVE Fill out this part if you are adding any new transgenic species.
Use of Transgenic Animals**

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|  | Yes | No |  |
|  | [ ]  | [ ]  | I am creating transgenic animals: (if yes, specify species and method):       |
| 1. .
 | [ ]  | [ ]  | I am breeding transgenic animals: (if yes, specify species and method):       |
|  | [ ]  | [ ]  | I am breeding rodents that have a gene encoding more than 50% of an exogenous eukaryotic virus. |
|  | [ ]  | [ ]  | I am breeding rodents in which the transgene is under the control of a gammaretroviral long-terminal repeat. |

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| **PART SIX Fill out this part if you are adding any novel gene delivery methods or new gene inserts.****Gene Delivery Methods Table** [See FAQs.](http://www.ehs.washington.edu/biological-use-authorization-bua-application-faqs#GD1) |
|  |
|  | 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). If additional spaces are needed, complete and submit the [Gene Delivery Methods Supplemental](http://www.ehs.washington.edu/resource/gene-delivery-methods-supplemental-biological-use-authorization-bua-application-705). For large numbers of genes, attach a complete list of genes. For large numbers of genes not yet identified, see question 29. If not introducing recombinant or synthetic DNA/RNA into cell culture, microorganisms, or animals, proceed to the next section. |
|  |
| 1. **Gene Delivery Method**

Choose from dropdown list | 1. [**Gene Inserts**](http://www.ehs.washington.edu/biological-use-authorization-bua-application-faqs#GD1)

**Must use common** [**RefSeq**](http://www.ncbi.nlm.nih.gov/refseq/rsg/) **gene names** | 1. [**In vitro**](http://www.ehs.washington.edu/biological-use-authorization-bua-application-faqs#GD2)

Specify cell type and activities | 1. [**In vivo**](http://www.ehs.washington.edu/biological-use-authorization-bua-application-faqs#GD3)

Specify species and activities | 1. **Source**

Choose from dropdown list |
| **EXAMPLE** | *GFP, viral LTR* | *[ ]* No *[x]* Yes:*grown in human cells; PCR analysis* | *[ ]* No *[x]* Yes:*Mice* |  |
|   |       | [ ]  No [ ]  Yes:      | [ ]  No [ ] Yes:      |        |
|   |       | [ ]  No [ ]  Yes:      | [ ]  No [ ] Yes:      |        |
|   |       | [ ]  No [ ]  Yes:      | [ ]  No [ ] Yes:      |        |
|   |       | [ ]  No [ ]  Yes:      | [ ]  No [ ] Yes:      |        |
|   |       | [ ]  No [ ]  Yes:      | [ ]  No [ ] Yes:      |        |
|   |       | [ ]  No [ ]  Yes:      | [ ]  No [ ] Yes:      |        |
|   |       | [ ]  No [ ]  Yes:      | [ ]  No [ ] Yes:      |        |
|  | Yes | No | N/A |  |
|  | [ ]  | [ ]  | [ ]  | Negative replication competent virus testing has been performed on the above viral vectors. See [EH&S webpage](http://www.ehs.washington.edu/resource/viral-vectors-gene-transfer-524) for viral vector testing information. If yes, submit results.       |

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| **PART SEVEN Fill out this part if you are adding any new gene inserts.****Gene Inserts**[See FAQs.](http://www.ehs.washington.edu/rbsresplan/faqs.shtm#geneinserts) |
| 1.
 | For research involving a large number of genes not yet identified, list the categories or general functions of the genes. [See FAQ.](http://www.ehs.washington.edu/biological-use-authorization-bua-application-faqs#GD1)       |
| Do any of the genes involved in this research influence the following (references to the *NIH Guidelines* are given). If yes, list the agent and explain. |
|  | Yes | No |  |
|  | [ ]  | [ ]  | Release of biological toxins ([*NIH Guidelines*, Section III-B-1](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.html) and [Appendix F](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.html)):       |
|  | [ ]  | [ ]  | 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](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.html)):        |
|  | [ ]  | [ ]  | Increase of tropism ([*NIH Guidelines*, Appendix B-V](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.html)):       |
|  | [ ]  | [ ]  | Increase of virulence ([*NIH Guidelines*, Section II-A-3](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.html)):       |

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| **PART EIGHT Fill out this part if you are adding any new gene inserts.****Oncogenes and Tumor Suppressor Genes**This section applies to work with oncogenes and tumor suppressor genes. [See FAQs for instruction on completing this section.](http://www.ehs.washington.edu/biological-use-authorization-bua-application-faqs#OG1) |
|  | Yes | No |  |
|  | [ ]  | [ ]  | Do any of your proposed genes appear in the following database (**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)

If yes, they are known oncogenes. List.       |
| 1. **CERTIFICATION**: **I have checked the above databases and have reported all genes that appear in them. PI Initials:**
 |  |
|  |
|  | [ ]  | [ ]  | Are any of your proposed genes well described in the scientific literatures as oncogenes? If yes, list genes and describe.       |
|  | [ ]  | [ ]  | Do you have other reasons to believe that your proposed genes are oncogenes? If yes, list genes and describe reasons.       |
|  | [ ]  | [ ]  | Do you have reasons to believe that you are silencing or knocking out tumor suppressor genes? If yes, list and describe.       |
|  | [ ]  | [ ]  | 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. [See FAQ](http://www.ehs.washington.edu/biological-use-authorization-bua-application-faqs#OG2).       |
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| **PART NINEFill out this part if you are adding any new recombinant agents, any new transgenic animals, or anything involving recombinant DNA.*****NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules***Select all sections of the *NIH Guidelines* that apply to this change. [See FAQs.](http://www.ehs.washington.edu/biological-use-authorization-bua-application-faqs#NIH1) |
|  | [ ]  |  | [Section III-A](http://www.ehs.washington.edu/system/files/resources/experiments-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](http://www.ehs.washington.edu/system/files/resources/experiments-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](http://www.ehs.washington.edu/system/files/resources/experiments-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](http://www.ehs.washington.edu/system/files/resources/experiments-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](http://www.ehs.washington.edu/system/files/resources/experiments-NIH-guidelines.pdf) | Experiments that require IBC notice simultaneous with 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](http://www.ehs.washington.edu/system/files/resources/experiments-NIH-guidelines.pdf) | [Exempt experiments](https://www.ehs.washington.edu/system/files/resources/exempt-experiments.pdf) (e.g., recombinant and synthetic DNA that is not in organisms or viruses, DNA/RNA in microorganisms that are exempt under III-F) |

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| **To the best of my knowledge, the information reported on this form is correct and accurately reflects my proposed research. I understand that I must contact UW EH&S Research and Occupational Safety prior to initiating any changes in my research involving biological and recombinant or synthetic DNA materials.**      Principal Investigator Name (printed or typed)           Principal Investigator Signature/Electronic Signature Date |
|  | Submit your completed application and supplemental documents to **EH&S Research and Occupational Safety****ehsbio@uw.edu** **· box 357165 · phone 206.221.7770 · fax 206.221.3068** Electronic submissions are preferred. |   |