**Clinical Trial BUA Application**

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

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| This application is for research projects that involve administration of recombinant or synthetic nucleic acids to human research participants. 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).  **Submit Application to:**  **EH&S Research and Occupational Safety**  [**ehsbio@uw.edu**](mailto:ehsbio@uw.edu) **· box 357165 · phone 206.221.7770 · fax 206.221.3068** |

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| **Protocol Title:** | | | | | |
|  | **Name** | **Daytime Phone** | **Email** | **UW NetID** | **Primary Institution of PI *(e.g., UW, FHCRC, Seattle Children’s, etc.)*** |
| **Principal Investigator** |  | .   . |  |  |  |
| **Protocol Contact Person** |  | .   . |  |  |  |
| **Anticipated Start Date:** | | **Funding Source(s):** | | **eGC-1 Number(s) (if applicable):** | |

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| **Human Research Participants** | | | | | | | | |
|  | | Yes | | | No |  | | |
|  | |  | | |  | This project involves human gene transfer as defined under [*NIH Guidelines*, Section III-C-1.](https://osp.od.nih.gov/wp-content/uploads/2019_NIH_Guidelines.htm#_Toc3457038) | | |
|  | |  | | |  | 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 documents (if applicable): | | | |
|  | |  | | |  | Yes | N/A |  |
|  | |  | | | a. |  |  | BUA clinical trial application |
|  | |  | | | b. |  |  | All correspondence with NIH Recombinant DNA Advisory Committee (RAC) (if available) |
|  | |  | | | c. |  |  | Clinical protocol |
|  | |  | | | d. |  |  | Investigator’s brochure (if available) |
|  | |  | | | e. |  |  | IBC approval from clinical trial site (if applicable) |
|  | |  | | | f. |  |  | FDA required modifications to the protocol (if applicable) |
|  | |  | | | g. |  |  | IRB approval (if available for renewals) |
| See the [EH&S website](https://www.ehs.washington.edu/biological/clinical-trials) for more information about research involving recombinant and synthetic DNA in human participants. | | | | | | | | |
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| **Institutional Review Board (IRB)** | | | | | | | | |
| 1. 4 | Which IRB is reviewing this study? | | | | | | | |
|  | Please list any IRB protocol numbers associated with this study. | | | | | | | |
| **Institutional Biosafety Committee (IBC)** | | | | | | | | |
|  | Please list all IBCs that are reviewing this study. | | | | | | | |
|  | Please list any IBC protocol numbers associated with this study. | | | | | | | |
| **Other Regulatory Bodies** | | | | | | | | |
|  | Please list the FDA IND number: | | | | | | | |
|  | Please list the NIH Human Gene Transfer Protocol number (format xxxx-xxxx), if known: | | | | | | | |
|  | Please list the protocol number (format xxxx.xx), if applicable: | | | | | | | |
|  | Please list any other associated numbers (sponsor numbers, etc.): | | | | | | | |
| **Study Information** | | | | | | | | |
|  | Is this an industry-sponsored trial? If so, please list the sponsor. | | | | | | | |
|  | Are there other sites where the trial is conducted or may be conducted in the future? If yes, please list: | | | | | | | |
|  | For renewals: please list the status of the trial (open to accrual, in long-term followup, closed, etc.) | | | | | | | |
|  | For new studies: when is the first research participant expected to be enrolled? | | | | | | | |
| **Contact Information** | | | | | | | | |
|  |  | | | Please list the name and email address for the person responsible for sending required reports (such as serious adverse events and annual reports) to the UW IBC. | | | | |
|  |  | | | **I**f different, please list the name and email address for the person responsible for sending required reports (such as serious adverse events and annual reports) to NIH Office of Science Policy. | | | | |
| **Hazard Assessment, Research Design, Anticipated Risks and Benefits, Informed Consent** | | | | | | | | |
| Objectives and Rationale of the Proposed Research | | | | | | | | |
|  | | | State concisely the overall objectives and rationale of the proposed study. Include the disease(s) to be treated, the cell type(s) to be genetically modified, if any, and a summary of the rationale for the treatment modality. If the therapy seeks to change patient DNA either in vivo or ex vivo in cells to be delivered, provide a high level overview. This should include: whether somatic cell or germ cell DNA will be changed; how it will be changed; and, if the change is an insertion, deletion, or other type of editing (if other type of editing, please provide detail). | | | | | |
| Product Description | | | | | | | | |
|  | | | Describe the derivation of the delivery vector system including the source (e.g., viral, bacterial, or plasmid vector); and modifications (e.g., deletions to attenuate or self-inactivate, encapsulation in any synthetic complex, changes to tropisms, etc.). Please reference any previous clinical experience with this vector or similar vectors. | | | | | |
|  | | | Describe the genetic content of the transgene or nucleic acid delivered including the species source of the sequence and whether any modifications have been made (e.g. mutations, deletions, and truncations). What are the regulatory elements contained in the construct? | | | | | |
|  | | | Describe any other material to be used in preparation of the agent (vector and transgene) that will be administered to the human research subject (e.g., helper virus, packaging cell line, carrier particles). | | | | | |
|  | | | Describe the methods for replication-competent virus testing, if applicable. | | | | | |
|  | | | Describe the intended ex vivo or in vivo target cells and transduction efficiency. | | | | | |
|  | | | Describe the gene transfer agent delivery method. | | | | | |
| **Recombinant DNA Advisory Committee Review** | | | | | | | | |
| The NIH Recombinant DNA Advisory Committee’s (RAC) review of individual human gene transfer protocols is limited to cases in which an oversight body (such as an Institutional Biosafety Committee (IBC) or an Institutional Review Board (IRB)) determines that a protocol would significantly benefit from RAC review. Please answer the questions below to determine if your study meets the criteria. | | | | | | | | |
|  | | | Does this protocol use a new vector, genetic material, or delivery methodology that represents a first-in-human experience, thus presenting an unknown risk? Please explain your answer. | | | | | |
|  | | | Does this protocol rely on preclinical safety data that were obtained using a new preclinical model system of unknown and unconfirmed value? Please explain your answer. | | | | | |
|  | | | Is the proposed vector, gene construct, or method of delivery associated with possible toxicities that are not widely known? Please explain your answer. | | | | | |

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| **Facilities**  List each UW research and/or clinical care space where you will perform work with biohazardous agents. Identify specific buildings, rooms, and activities. Include specific pharmacy rooms and infusion suites. |

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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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|  | **Human Research Participant Use** | | | |
| **Building/Room** | | **Activities** | **Biohazardous Agents** | **Comments** |
| *UW Medical Center 7NE*  **EXAMPLE** | | *Infusion of genetically modified cells* | *Human donor T lymphocytes transduced with a gammaretroviral vector* | *Administered to participant at BSL-2.* |
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| Principal Investigator Statement of Responsibility   * As Principal Investigator for this project, I understand that I am responsible for assuring that my research complies with all federal, state, and local environmental laws and regulations. I have the responsibility to ensure that my laboratory operates in a safe manner and that all staff and students are informed of risk, appropriately wear protective equipment, and are adequately trained. * 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 ensure that no human gene transfer experiment be initiated until IBC approval (from the clinical trial site) is obtained; and all other applicable institutional and regulatory authorization(s) and approvals have been obtained. * I will report the following to an EH&S biosafety officer at 206-221-7770 or [ehsbio@uw.edu](mailto:ehsbio@uw.edu) as soon as possible:   + (1) Violations of the *NIH Guidelines*;   + (2) Biohazardous spills or loss of biohazard containment;   + (3) Research-related accidents or illnesses;   + (4) Exposures or potential exposures to biohazards, including recombinant or synthetic DNA/RNA; * I will adhere to the IBC-approved emergency plans for [handling accidental spills](https://www.ehs.washington.edu/system/files/resources/spill-response-poster.pdf) and [personnel exposures](https://www.ehs.washington.edu/system/files/resources/exposure-response-poster.pdf). * In case of incidents or near misses, I will instruct my staff to complete the [Online Accident Report (OARS)](https://www.ehs.washington.edu/workplace/accident-and-injury-reporting) form within 24 hours. If any of my staff are employed by the University of Washington Medical Center or Harborview Medical Center, then I will direct them to complete an accident report on the Patient Safety Network (PSN).   **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 materials (including recombinant or synthetic DNA/RNA).**    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**](mailto:ehsbio@uw.edu) **· box 357165 · phone 206.221.7770 · fax 206.221.3068**  Electronic submissions are preferred. |  | |