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**Office of Environmental Health and Safety**

**Viral Vectors Subform - Biosafety Permit Application**

**Instructions:**

* This subform is to be used in conjunction with the biosafety permit application form or a biosafety permit amendment form. Once completed, save as pdf and submit along with your application form.
* Please fill one form per viral vector system employed.

|  | **Questions** | **Response** |
| --- | --- | --- |
| 1 | Type of viral vector used (choose one of the following):   * Adenovirus Associated virus-based vectors * Adenovirus-based vectors * Lentivirus-based vectors * Other Retrovirus-based vectors * Other virus-based vectors (describe) |  |
| 2 | Parental virus, including type |  |
| 3 | Describe the overall goal(s) and anticipated outcomes of the research project (1-5 sentences should be sufficient). |  |
| 4 | Describe how the viral vector is involved in the overall project. |  |
| 5 | Will the vector particles be injected into live animals?   * Yes * No |  |
| 6 | Are the vector particles generated in the lab, commercially sourced, or acquired from a collaborator?   * Generated in lab * From collaborator * Commercially sourced |  |
| 7 | If generated in the lab, provide all plasmids used for transfection and the cell line(s) used. Provide the risk groups of the cell lines. |  |
| 8 | What is the cell tropism and host range of the vector particles?  Have the sequence of the viral vector surface glycoproteins or other proteins been modified to change the cell tropism and/or host range of the parental virus? If so, briefly describe the modifications and how they affect cell tropism and host range. |  |
| 9 | Is the viral vector non-replicating in target cells? In producer cells? What makes it non-replicating? |  |
| 10 | Can the viral vector recombine with other sequences in producer cells or target cells to generate replication competent virus? Explain. |  |
| 11 | Provide a simple diagram showing a gene annotated organization of the vector genome. Indicate the genes that have been deleted to render the virus replication incompetent (if relevant). |  |
| 12 | What is the promoter driving the transgene in the viral vector? |  |
| 13 | Nature of the inserts. Indicate if they are:   * reporter genes – list the inserts * host genes – if known to be oncogenes then list the inserts * viral genes– list the inserts |  |
| 14 | Function of the transgene(s), if known. |  |
| 15 | If vector particles are being generated in the lab, list the manipulations/methodologies that are used. Include centrifugation steps. |  |
| 16 | Typical titer of the vector particle stock |  |
| 17 | Typical volume handled at one time (for purification or for experiment). |  |
| 18 | Are you using needles? If yes, what safety precautions are in place for the user? |  |
| 19 | Potential routes of exposure and mitigation strategies (e.g. aerosol – BSC, aerosol tight centrifugation, needlestick).  Highlight biosafety practices that are in place for safe handling and transport of infectious material. |  |
| 20 | What are the potential consequences of exposure?  *Note:*  If exposed:  1) Notify your PI  2)Submit an incident report to EHS: <https://ehs.utoronto.ca/report-an-incident/> |  |
| 21 | If accidently infected with the viral vector, are there conditions, including medical conditions in which the viral vector could replicate? If yes, explain. |  |
| 22 | Post exposure prophylaxis (where applicable) |  |
| 23 | Decontamination procedures (disinfectant used, waste treatment, spill response) |  |

**Reference Information:**

**Common Lentiviral Vectors that are Pseudotyped with Surface Glycoproteins of Other Viruses**

|  |  |  |  |
| --- | --- | --- | --- |
| **Envelope Protein** | **Source** | **Tropism** | **Other Information** |
| **VSV-G** | Vesicular stomatitis virus G protein | Broad including multiple tissues within the host, including Humans | Inactivated (only about 2 logs) by the complement system in serum (https://pubmed.ncbi.nlm.nih.gov/10985952/) |
| **MLV** | Moloney Murine leukemia virus | Murine restricted |  |
| **LCMV** | Lymphocytic choriomeningitis virus | Murine, Human |  |

**AAV Serotypes**

|  |  |
| --- | --- |
| **AAV Serotype** | **Tropism** |
| **AAV1** | CNS, Heart, Retinal Pigment Epithelium, Skeletal Muscle |
| **AAV2** | CNS, Kidney, Photoreceptor cells, Retinal Pigment Epithelium |
| **AAV3** |  |
| **AAV4** | CNS, Lung, Retinal Pigment Epithelium |
| **AAV5** | CNS, Lung, Photoreceptor cell, Retinal Pigment Epithelium |
| **AAV6** | Lung, Skeletal Muscle |
| **AAV7** | Liver, Skeletal Muscle |

**References:**

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1368960/>

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5571256/>

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| --- | --- | --- | --- |
| **Form Version History** | **Date** | **Summary of Changes** | **Approved by (Name and Role)** |
| 2.0 | Nov 6, 2024 | Revisions of some questions for better clarity | Martha Brown, Arinjay Banerjee, Viral Vector SMEs  Ayoob Ghalami, Institutional Biosafety Officer |
| 1.1 | Oct 6, 2023 | Addition of Question 1 | Martha Brown, Arinjay Banerjee, Viral Vector SMEs  Ayoob Ghalami, Institutional Biosafety Officer |
| 1.0 | Oct 4, 2023 | Additional Questions | Martha Brown, Arinjay Banerjee, Viral Vector SMEs  Ayoob Ghalami, Institutional Biosafety Officer |
| 0.1 | 2022 | Initial Form | Martha Brown, Alan Cochrane, Viral Vectors SMEs  Ayoob Ghalami, Institutional Biosafety Officer |