**University of Rochester Institutional Biosafety Committee**

#### Form

**VVV**

# *Mammalian Viral Vector System Registration Form*

Principal Investigator: Dept: Phone:

Co-Principal Investigator: Dept: Phone:

Technician or Alternate Contact: Phone:

***Complete this document for the infectious, recombinant viruses you possess which were constructed to deliver or transport desired inserts into cells for the purposes of insert expression.***

***This document*** *must be completed individually* ***for each viral base*** *(i.e. adenovirus, lentivirus, etc.) even if more than one is proposed for one project.*

The Mammalian Virus Vector Registration Form provides supplemental information to the IBC to help determine the appropriate biosafety precautions for your particular viral construct(s). Do not submit this form by itself; it must be accompanied by a Grant/Project registration (G-form).

Complete and submit this form electronically as a Word e-mail attachment to the IBC Program Coordinator [ddouglass@safety.rochester.edu](mailto:ddouglass@safety.rochester.edu).

Useful references:

* + - * [IBC web pages](http://www.safety.rochester.edu/homepages/ibchome.html)
      * [Additional guidance for virus vectors](http://www.safety.rochester.edu/ibc/pdf/ibcvirus.pdf)
      * [NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules](http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines)
      * Biosafety Officer (275-3014 or [srosen22@safety.rochester.edu](mailto:srosen22@safety.rochester.edu))
      * IBC Coordinator (275-2402 or [ddouglass@safety.rochester.edu](mailto:ddouglass@safety.rochester.edu))

VV1. What vector system are you registering with this document?

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Adenovirus Vector |  | Adeno-associated virus vector |  | Retrovirus vector |
|  | Herpes vector (Amplicon-type) |  | Herpesvirus vector (Standard) |  | Lentivirus vector |
|  | Poxvirus vector |  | Other mammalian virus, specify: | | |

VV2. Will your lab play any part in constructing and producing the infectious virus? (e.g., cloning insert, transfecting plasmids into packaging cells, purification or isolation of virus)

|  |  |  |  |
| --- | --- | --- | --- |
| YES |  | NO |  |

If you will be receiving the infectious virus from someone, please indicate source:

VV3. Virus vector characteristics and production:

1. List the **name and source** of all vector backbone(s), packaging plasmid(s). Include if VSV-G pseudotyped.
2. If you are using the vector for gene ablation (e.g. CRISPR/Cas9), will the construct result in the creation of a **gene drive** or selfish genetic element (i.e. a higher chance of a gene being inherited than by Mendelian genetics)? Explain why or why not.
3. Describe your **production methods**, including packaging or producer cell lines and *E. coli* strains for plasmid propagation. Will production involve centrifugation or filtration (indicate whether syringe or vacuum based filtration)? Needles or other sharps?
4. Does your vector system include a **helper virus** (e.g., some AAV systems, herpes virus amplicons)? If so, is this helper virus inactivated or attenuated? How much infectious helper virus remains in your vector inoculum?
5. What genes are deleted from your vector and/or its helper virus (e.g. E1A/E1B/E3/E4 for adenovirus; IE/TK for herpes; gag/pol/env/tat/rev for lentivirus; TK for pox; HA for pox; gag/pol/env for retrovirus)? Is your vector system **replication defective**? Is your vector system **self-inactivating** (i.e. truncated 3’ LTR)?
6. What is the **potential that wild-type virus will be produced** during the *in vitro* generation of virus stocks? Provide any evidence that supports your estimate (published or otherwise). Will you monitor production of wild-type virus and if so, how? **If you do not know what the frequency of virus reversion is, you must state this clearly in your lab operating procedure and anyone handling the virus in your lab must be apprised of this risk.** Please think carefully about additional aspects of the recombinant virus, particularly as they may relate to (i) potential for regeneration of infectious virus, (ii) pre-existing presence of such virus in your starting material, (iii) recombination with wild-type virus (if present in the environment).
7. What **experience** do you have working with this virus? If you have none, will you collaborate with someone who is experienced? If so, who?

VV4. Questions relating to the nature of recombinant DNA sequences transduced by the virus:

Questions in the following table must be answered for each distinct gene/construct. Add rows to the table as needed for additional constructs.

NOTE: It is forbidden to insert any variola sequence into any pox-based vector. Also, individuals working with variola virus sequences must be physically separated from experiments involving other poxviruses (i.e., if the sequences are being expressed in *E. coli*, other experiments with poxviruses must not occur in the same room or equipment).

Please also note this list of questions is incomplete; think carefully about the specifics of your gene. Remember that although your recombinant may not be able to replicate on its own, many viruses (e.g., adenoviruses, herpes viruses, AAV) are common in the environment and contagious, and co-infection with a wild-type virus will result in the spread of the recombinant through aerosols and/or feces.

Comments:

**(to e in the following table) What adverse effects might result from inhaling or otherwise ingesting the recombinant virus containing your cloned genes?** *For example: adenovirus can replicate in the respiratory tract and the gut; AAV may survive passage through the GI tract.* If this would result in the expression of your gene in tissue(s) where it normally is not expressed, what effects might this have? Explain in detail below.

**(to f in the following table) Is your gene involved in cell growth control (i.e., oncogene, tumor suppressor, cytokine)?** Might this result in tumor induction? Is there a risk of oncogenesis as a result of viral insertion into the host chromosome?

**(VV4. Questions relating to the nature of recombinant or synthetic nucleic acid sequences transduced by the virus, continued):**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| (a) | (b) | (c) | (d) | (e) | (f) | (g) |
| Insert | Nucleic acid type | Species of origin | Expression (Promoter) | Insert name  Potentially adverse effects? | Involved in cell control? | Pathogenic conversion? |
| Expression | | | | | | |
| Gene symbol, preferably in alphabetic order | *ex.* genomic, cDNA, microRNA, etc. |  |  | Insert name, then list potentially adverse effects (*ex*: oncogenic potential, toxic, pro-inflammatory) | *ex*: proliferation, cell survival |  |
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|  |  |  |  |  |  |  |
| Insert | Nucleic acid type | Species of origin | Expression (Promoter) | Insert name  Potentially adverse effects? | Involved in cell control? | Pathogenic conversion? |
| Antisense or Knockout | | | | | | |
| Gene symbol, preferably in alphabetic order | *ex:* shRNA, siRNA, sgRNA for CRISPR, etc. | or, species homology for sgRNA |  | Insert name, then list potentially adverse effects (*ex*: oncogenic potential, toxic, pro-inflammatory) | *ex*: proliferation, cell survival |  |
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**Revised 8/16/16**