University of Rochester Institutional Biosafety Committee
Mammalian Viral Vector System Registration Form

Form
VV

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 system*** *even if all systems are 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).

Please submit to the IBC as a PDF or Word e-mail attachment (ddouglass@safety.rochester.edu). Be sure to save a copy on your computer for future modification.

Specific guidelines and resources can be found under EXTENDED HELP.
http://www.safety.rochester.edu/ibc/extendedhelp.html

Useful references:

NIH Guidelines:
http://oba.od.nih.gov/rdna/nih_guidelines_oba.html

CDC/NIH "Biosafety in Microbiological and Biomedical Laboratories"
http://www.cdc.gov/biosafety/publications/bmbl5/index.htm

IBC web pages
http://www.safety.rochester.edu/homepages/ibchome.html

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 system:

a) **Name and source** of viral vector system. List all plasmids that are part of the system.

b) Describe your **production methods**. Is the transfection transient? Will you be using packaging or producer cell lines? If yes, please list them and their organism of origin. (e.g., human, insect, mouse). Will production involve centrifugation or filtration (indicate whether syringe or vacuum based filtration)?

c) 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?

d) 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** or **replication competent**?

e) Will you use greater than 2/3 of a Risk Group 2 or 3 virus as the vector or as an insert?
(HINT: This would be YES for most E1-deleted, replication–defective adenovirus vectors but NO for most replication-defective retrovirus vectors)

f) What is the host range or **tropism**? Please indicate species. Have any changes been made to the natural host range or tropism? If yes, please describe altered tropism.

g) 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).

h) 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 g 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 DNA sequences transduced by the virus, continued):

(a)	(b)	(c)	(d)	(e)	(f)	(g)
Insert name	**DNA type**	**Species of origin**	**Expression (Promoter)**	**Potentially adverse effects?**	**Involved in cell control?**	**Pathogenic conversion?**
	ex. genomic, cDNA, antisense, other			*ex*: oncogenic potential, toxic, pro-inflammatory	*ex*: proliferation, cell survival	

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[EHS Web/IBC/doc/mammalianregform]