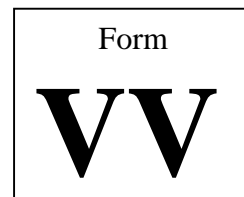


**University of Rochester Institutional Biosafety Committee
Mammalian Virus Vector Registration Form**



Principal Investigator: _____ Dept: _____ Phone: _____

Co-Principal Investigator: _____ Dept: _____ Phone: _____

Technician or Alternate Contact: _____ Phone: _____

NOTE: This form must be completed individually **for each vector system** you are using even if all vectors are proposed for one project. The Mammalian Virus Vector Registration Form (VV) is a supplemental form to provide the IBC with information necessary for determining appropriate biosafety precautions for your particular viral construct(s). This form must be accompanied by a lab registration (LAB) and Grant/Project registration (GNT) or project modification (AM) form.

For YES/NO questions, please place an “X” in the box next to the correct answer. Please submit to the IBC as a PDF or Word e-mail attachment (pbardeen@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**.

Mammalian Virus Vector help: www.safety.rochester.edu/ibc/ibcvirus.htm

FIV vector help: <http://www.safety.rochester.edu/restricted/fivguidelines.html>

Adenovirus help: <http://www.safety.rochester.edu/restricted/adenovirusguidelines.html>

Useful references are the NIH Guidelines <http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html> , the 5th edition of CDC/NIH “Biosafety in Microbiological and Biomedical Laboratories” <http://www.cdc.gov/od/ohs/biosfty/bmb15/bmb15toc.htm>, and the IBC web pages <http://www.safety.rochester.edu/ibc/index.html> . Questions can be referred to Janet Ives, Biosafety Officer (274-3014; jives@safety.rochester.edu) or to Dr. Pavelka, Chair, IBC (275-4670; martin_pavelka@urmc.rochester.edu).

Note on human gene transfer proposals: Please inform the IBC as early as possible when you are considering submission of a human gene transfer proposal. Early notification and timely submission of complete materials will expedite the review.

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

<input type="checkbox"/>	Adenovirus Vector	<input type="checkbox"/>	Adeno-associated virus vector	<input type="checkbox"/>	Retrovirus vector
<input type="checkbox"/>	Herpes vector (Amplicon-type)	<input type="checkbox"/>	Herpesvirus vector (Standard)	<input type="checkbox"/>	Lentivirus vector
<input type="checkbox"/>	Poxvirus vector	<input type="checkbox"/> Other mammalian virus, specify:			

VV2. Will your lab play any part in vector preparation prior to its use?

<input type="checkbox"/> YES	<input type="checkbox"/>	<input type="checkbox"/> NO	<input type="checkbox"/>
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If you will be receiving the prepared vector from someone, please indicate source:

VV3. Are your constructs capable of and/or will your experiments involve:

- a. Deliberate formation of rDNAs containing genes for biosynthesis of toxic molecules?

YES		NO	
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- b. Deliberate release into the environment any organism containing rDNA?

YES		NO	
-----	--	----	--

- c. Use of other than a Risk Group 1 agent as a host-vector system? (See Appendix B of NIH Guidelines)

YES		NO	
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- d. Administration rDNA to humans?

YES		NO	
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- i. If yes, what protein/RNA will be expressed?

- e. Is rDNA to be used for production of transgenic or knockout animals?

YES		NO	
-----	--	----	--

- i. If yes, what is the animal species?

- ii. What is the gene to be expressed or knocked out?

- f. Will experiments ever involve more than 10 liters of culture?

YES		NO	
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- g. 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)

YES		NO	
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VV4. Virus vector system:

- a) **Name and source** of viral vector system. List all vectors 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 the source from where they will be obtained. Will production involve centrifugation (indicate *rcf* used) 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) 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.

- f) 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 vector, 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).
- g) What **experience** do you have working with this virus? If you have none, will you collaborate with someone who is experienced? If so, who?

VV5. 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?

