

LENTIVIRAL VECTOR RISK ASSESSMENT SHEET

For assistance, please contact OSEH (734) 763-6973, or visit our web site at www.oseh.umich.edu

The information below represents a summary of the guidance issued by the National Institutes of Health, which is posted in full at:

http://oba.od.nih.gov/oba/rac/Guidance/LentiVirus_Containment/pdf/Lenti_Containment_Guidance.pdf.

Introduction – Lentiviruses

Lentiviruses comprise a genus of the Retroviridae family and include human, simian, feline, bovine, equine lentiviruses (the immunodeficiency viruses such as HIV, FIV, SIV).

Risks of Lentivirus Vectors – NIH Guidance

The major risks to be considered for research with HIV-1 based lentiviral vectors are:

- The capability for generation of replication-competent lentivirus (RCL);
- The potential for oncogenesis or other deleterious effect through insertional mutagenesis.

The mitigation of these risks can be achieved through vector design (ex. 2nd or 3rd generation systems), however, or exacerbated by the nature of the transgene (ex. any gene involved in cell growth, death, or apoptosis, or that may otherwise be toxic to the cell).

There may be increased risk potential for HIV positive individuals whose native virus may recombine with the recombinant virus. Such individuals are encouraged to disclose this information to their supervisor.

Use the information above along with the elements of the table below to perform a risk assessment of the lentiviral vector construct you will be using. You will need to provide a thorough risk assessment considering the **vector design, transgene, vector propagation, and if applicable, animal hosts and manipulations, as part of your IBC Registration.**

Biosafety Considerations and Risk Levels		
Biosafety Considerations	Higher Risk	Lower Risk
Vector Design	<ul style="list-style-type: none"> - Vector packaging functions on two plasmids - Expression of viral genes 	<ul style="list-style-type: none"> - Vector and packaging functions separated onto multiple plasmids - Deletion of viral genes
Transgene	Oncogenic, apoptotic, or otherwise toxic	Non-oncogene, non-apoptotic, or otherwise non-toxic
Vector Propagation	Large scale	Laboratory scale
Animal Hosts	<ul style="list-style-type: none"> - Permissive host - Animals engrafted with human cells 	Non-permissive host
Animal Manipulations	Vector administration (e.g., use of sharps during injection)	Housing and husbandry (no use of sharps)

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