

**UNIVERSITY OF CALIFORNIA SAN FRANCISCO
BIOSAFETY COMMITTEE**

**VIRAL VECTOR/GENE/CONSTRUCT EXPOSURE RISK ASSESSMENT SUMMARY
PART 1**

**A viral vector information summary should be completed for each infectious construct
BEFORE IT IS USED in research**

Principal Investigator: _____

Location (campus/building/room): _____

Principal Investigator 24/7 Contact Information: _____

Viral Vector (genus/species/strain): _____

Specify Source: _____

(commercial vs. laboratory derived-which lab, etc.)

Specify Vector Tropism: _____

(ecotropic, amphotropic, tissue type, etc.)

Is this vector capable of infecting human cells? YES NO NOT SURE
If no, stop here. If yes, or not sure, continue to provide the information requested below

PART I. Emergency Response Plan

Each PI must develop an emergency response plan in case of exposure to viral vectors. It is the responsibility of the PI to provide risk assessment information and guidance to medical providers at the time of exposure and support to injured lab employees throughout their medical evaluation.

The first step is to perform a risk assessment for each viral construct backbone that will be used. This is based on the potential hazards of the vector and an analysis of the hazards of each expressed gene included in the construct. The PI must define what constitutes a significant exposure based on a risk assessment for each viral construct backbone. For most viral vectors, this would include percutaneous exposure, exposure to non-intact skin and mucosal splashes from high titer preparations. If laboratory animals are used in the protocol, consideration must also be given to the hazards of animal bites.

Points to consider include: What are the hazards of the transgenes? In general, transgenes of major concern include potential oncogenes, genes that modulate immune response and genes coding for “immunologically privileged proteins”, i.e. proteins that are not normally seen by the immune system, against which induction of an immune response could result in an autoimmune syndrome. Consideration should also be given to the possibility of recombination between viral vectors and endogenous viruses containing homologous sequences and to the presence of replication competent viral contaminants present after production of the vector. If you need advice or assistance in completing this risk assessment, please contact the UCSF Biosafety Officer or alternates, listed below.

In case of exposure, part I should be available for review by the exposure hotline practitioner and/or Hospital Emergency Department. The exposure hotline (353-7842) for all areas except SFGH; 469-4411 at SFGH) will provide immediate medical advice, and facilitate referral for more definitive evaluation at the UCSF/Mount Zion Occupational Health Service. A copy this form, including part II (see below), must be sent by email to the Biosafety Officer, the Chair of the Biosafety Committee, and Mt. Zion/UCSF Occupational Health Service within 24 hours.

**UNIVERSITY OF CALIFORNIA SAN FRANCISCO
BIOSAFETY COMMITTEE**

**VIRAL VECTOR/GENE/CONSTRUCT EXPOSURE RISK ASSESSMENT SUMMARY
PART 1**

PLEASE NOTE: This form is ONLY required for Lentivirus, Adenovirus, and/or other Risk Group 2 viral vectors. In case of exposure, a copy of this form must be sent by e-mail to the Biosafety Officer at peili.zhu@ucsf.edu.

Is the vector replication competent? _____

List all viral genes present in the viral vector:

List all transgenes present in the vector: _____

Does the vector contain genes expressing or inhibiting the target of DNA/RNA segments that encode substances that are immunogenic, (proto)oncogenic, teratogenic, toxigenic or enhance pathogenicity?

Briefly describe risks to researchers if exposed to viral vector, gene(s), and/or construct(s):

If significant exposure occurs, describe emergency procedures: _____

**UNIVERSITY OF CALIFORNIA SAN FRANCISCO
BIOSAFETY COMMITTEE**

**VIRAL VECTOR/GENE/CONSTRUCT EXPOSURE RISK ASSESSMENT SUMMARY
PART II**

(TO BE COMPLETED AFTER ACCIDENTAL EXPOSURE)

PART II. IN CASE OF EXPOSURE, COMPLETE THE FOLLOWING:

(This information must be submitted to the UCSF Biosafety Officer, the Chairman of the Biosafety Committee, and the Mt. Zion/UCSF Occupational Health Service WITHIN 24 HOURS)

Provide contact information for the PI/Laboratory manager in case further information is needed. Include email address/office phone/cell phone/pager numbers, etc.: _____

Describe the exposure in detail: _____

Which vector was the employee exposed to? Specify all viral sequences and transgenes present in the vector: _____

Evaluate Transgene Risks:

- Does the transgene modulate immune response? _____
 - (Are there any genes that may interfere with host immune response and make the construct more pathogenic?)
- Does the transgene code for an immunologically privileged protein? _____
 - (a protein not normally seen by the immune system, against which induction of an immune response could result in an autoimmune syndrome?)
- Is the construct potentially oncogenic? _____

Was the Exposure Hotline contacted and when was it contacted? _____

Has the exposed employee been referred to the Mt. Zion/UCSF Occupational Health Service? _____

If the vector was designed to be replication deficient, it should be assayed for replication competence following human exposure. Assay results should be sent to the Biosafety Officer, the Chair of the Biosafety Committee, and the Mt. Zion Occupational Health Service within 5 working days.

Important Contact Information:

- Mount Zion/UCSF Occupational Health Service: Telephone 415 885-7580, Fax 415 771-4472
- UCSF Exposure Hotline Pager: 415 353-7842 or 415 469-4411 for SFGH
- UCSF Biosafety Officer: Peili Zhu MD, PhD, Telephone 415 514-2824 Email: Peili.zhu@ucsf.edu
- UCSF Public Health Officer: Krista Lindstrom DVM, MPH, Telephone 415 514-3531 Email: krista.lindstrom@ucsf.edu (alternate contact for the Biosafety Officer)
- UCSF Assistant Biosafety Officer: Jonathan Koolpe BA, MS, Telephone 415 502-1799 Email: Jonathan.Koolpe@ucsf.edu (alternate contact for the Biosafety Officer)
- Chair of UCSF Biosafety Committee: Mike McGrath MD, Telephone: 415 206-8204 Email: MMcGrath@php.ucsf.edu