Welcome to the Viral Vector Hazard Identification Tool. This tool is intended to assist the Biosafety Professional in identifying risk factors at play with the use of a specific viral vector. This process begins with identifying the hazards associated with the parent virus, then delineating modifications in hazard due to any molecular engineering of the vector. Next, the process identifies hazards present due to the payload or insert of the viral vector; and last, this process identifies hazards due to the setting or mode of application.

Please note that this tool does NOT assess the probability of damage occurring due to the hazards identified and therefore is not a substitute for a complete risk assessment performed by the Biosafety Professional, the PI or laboratory worker, and/or the IBC that takes into account manipulation(s) of the viral vector.

1. Identifiers

Name of viral vector:

Parent virus:

Parent virus strain:

Individual completing risk assessment:

Education and background:

Years of experience with this vector:

Years of experience with similar vectors:

2. Parent Virus Hazard ID

Describe the parent virus origin and provide references or copies of any associated case notes or reference(s) describing its original isolation:

Describe the parent virus infection cycle, natural route(s) of transmission, binding and entry mechanism if known, infectious doses via those routes, disease severity in healthy human adults and molecular mechanism if known, risk factors or at-risk populations for more severe forms of disease, and effective prophylaxes or other therapeutic interventions:

Identify the parent virus environmental stability and effective chemical disinfectant(s) and/ or physical decontamination measures:

3. Nature and Source of Viral Vector

How novel is the viral vector? Well-establishe

Describe the genetic system used to express the viral vector particles:

Describe the safety features engineered into the genetic system:

Is the viral vector replication-competent? Impaired or con

Describe the modifications made to the previous generation of this vector and their impact (if any) on: host range, infection cycle, immune response, disinfectant efficacy and/or antiviral efficacy.

Identify any virulence factors that have been removed or impaired and the method used to do so:

Has the viral vector tropism been modified from the parent virus or parent viral vector? If so, please describe the modification and the altered tropism:

In your professional opinion, what is the potential for a host immune response to the viral vector? High

Is the viral vector known to be shed or processed (via immune system or catabolic pathways) by a different route than the parent virus? If so, please describe route(s) and kinetics if known:

How will the viral vector be acquired? Acquired from a commercial vendor

What are the quality control measures in place to guarantee minimal chance of recombination, reversion, or breakthrough:

If made in -house, what measures are taken by the lab to ensure no cross-contamination of the viral vector with other viral vectors, minimize risk of accumulating mutations and/ or recombination, and minimize risk of personnel exposure and/or release?

If acquired from a collaborator or vendor, what safety measures are recommended by the provider of this viral vector?

4. Viral Vector Payload

Payload Information (attach spreadsheet if insufficient space provided below)

Gene (or representative examples)	Classification (e.g. oncogene, transcription factor, marker/tag)	Payload Form (e.g. mRNA, siRNA, guide RNA + CRISPR, transgene)

Is the viral vector intended for use in the study of a disease or an intervention to a disease?
Yes ◯ No ◯

If Y: Provide the disease name and a description of the disease:

Does the viral vector or its payload integrate into the host genome? Yes ◯ N o ◯ Unknown ◯

If yes, is the integrated genetic element mobilizable? Yes ◯ No ◯

Does the viral vector payload or backbone persist in the host cell? Yes ◯ N o ◯ Unknown ◯

In your professional opinion, what is the potential of the viral vector – including the payload – to disrupt homeostasis of the host cell? Medium

If potential is medium or high, is there a reasonable expectation that this disruption of homeostasis will result in cell or tissue malfunction or other disease? If so, please describe:

In your professional opinion, what is the potential of the payload to initiate an immune response from the host? High

In your professional opinion, what is the potential of the viral vector – including the payload – to alter or disrupt the host immune system? High

(for High or Medium): Is there a reasonable expectation that this immune system disruption will predispose the host to infection or other disease? If so, please describe:

5. Use Modality

Will this/these vectors be used in cell/tissue culture? Yes ◯ No ◯

Please describe which construct(s) will be inoculated into which cell line

Vector	Payload Gene	Cell Line	Cell Line Origin (e.g. human, mouse, Chinese hamster)

What is the expected maximum viral vector titer in culture?

What measures are taken by the lab to ensure no cross-contamination of the viral vector with other viral vectors, and minimize risk of personnel exposure and/or release?

What samples will be collected from these cell lines and when?

How will the vector-inoculated cells be used?

Will the samples be fixed or otherwise be treated to inactivate any viral vector present prior to analysis? If so, how?

Will this/these constructs be administered to research animals?

What is the host species for this study?

Approved animal study number and expiration date (or anticipated approval date):

What are the species-specific risks to research and animal care staff?

What type of material will be administered to the animals (e.g. purified vector, vector-modified cells)?

If administering vector-modified cells, provide details regarding how long (time or number of passages) after inoculation the cells will be maintained prior to administering them to the animals. Will replication-competent vector be present in the cells, and how will this be confirmed?

What is the route of administration?

What is the dose being delivered?

What are the anticipated shedding kinetics of this viral vector using this route of administration and dose?

Is this viral vector expected to alter host animal behavior in any way? Yes ◯ No ◯

If yes, please describe:

What samples will be collected from the research animals and when?

Describe the intended use and disposition of all samples taken from animals after the viral vector has been administered.

Will the samples be fixed or otherwise be treated to inactivate any viral vector present prior to analysis? Yes ◯ No ◯

If yes, please describe.

Will this/these constructs be used in human clinical studies? Yes ◯ No ◯

List which vector/payload(s) will be used in human clinical studies:

Does the viral vector have approval from the FDA for this use? Yes ◯ No ◯

If yes: FDA IND number:

Do you have any unanswered questions about the safety of this viral vector after reviewing the preclinical data? Yes ◯ No ◯

If yes, please list:

Has your IRB addressed relevant risks to the patient receiving the viral vector? Yes ◯ No ◯

What are the risks to the clinical staff preparing or administering the vector?

Have those risks been conveyed to the clinical staff? Yes ◯ No ◯

What are the risks to close contacts of the patient?

Have they been conveyed to those individuals? Yes ◯ No ◯

Will this/these vectors be introduced to plants? Yes ◯ No ◯

What is the host species for this study?

What is the method of delivery for this viral vector?

What is the dose being delivered?

Will this be a field release? Yes ◯ No ◯

Is this viral vector intended to propagate throughout plant tissue? Yes ◯ No ◯

If yes, please describe:

Is this viral vector expected to shed from plant tissue after delivery? Yes ◯ No ◯

If yes, what are the shedding kinetics of this viral vector using this route of administration and dose?

Is this viral vector expected to be found in the soil after administration? Yes ◯ No ◯

Will this/these vectors be administered to arthropods? Yes ◯ No ◯

What is the arthropod species to be used in this study?

What is the method of delivery for this viral vector?

What is the dose being delivered?

Is the payload expected to be transmitted transtadially? Yes ◯ No ◯

Is the payload expected to be transmitted transovarially? Yes ◯ No ◯

Is the payload expected to be transmitted by feeding? Yes ◯ No ◯

Where in the arthropod is the payload expected to be expressed?

Is this viral vector expected to shed from the arthropod after inoculation? Yes ◯ No ◯

If yes, what are the anticipated shedding kinetics of this viral vector using this route of administration and dose?

Will the arthropods be capable of producing viable offspring? Why or why not?

Will the arthropods be part of a field release? If yes, provide details.

6. Engineering Controls and PPE

Location

Activity	Proposed Location	Containment Level

Available Safety Equipment

- ☐ Class I BSC
- ☐ Class II BSC
- ☐ Class III BSC
- ☐ Other:
- ☐ Biocontainment Centrifuge
- ☐ Biocontainment Animal Caging
- ☐ Filtered Micropipette Tips
- ☐ Single Use Needle
- ☐ Single Use Scalpel
- ☐ Blunt Tipped Scissors

PPE

- ☐ Front Close Gown
- ☐ Back Close Gown
- ☐ Tyvek Suit
- ☐ Safety Glasses
- ☐ Single Gloves
- ☐ Double Gloves
- ☐ Cut Resistant Gloves
- ☐ Safety Goggles
- ☐ N95/N100
- ☐ PAPR
- ☐ Face/Dust Mask
- ☐ Other:
- ☐ Hair Cover
- ☐ Shoe Cover
- ☐ Heavy Apron