**GM Risk Assessment Form**

**Genetically Modified Viruses and Virus Vectors (GMV és GMVV)**

A GM risk assessment for human health and the environment should be carried out for any work involving the use of genetically modified Viruses and Virus Vectors. The completed form shall be retained and made available to the gene technology authority upon request. Please read the guidance provided on GM risk assessment, which is available [here](https://gmo.kormany.hu/download/2/e8/13000/K%C3%89%20t%C3%A1j%C3%A9koztat%C3%B3%20final.pdf).

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| **1. General information** |
| The purpose of the activity |
| Click here to enter text. |
| The number of the existing official permit | Click here to enter the number of permit. |
| Name of the Institute | Click here to enter text. |
| Location of work (Building and room numbers) |
| Click here to enter text. |
| The number of the existing official permit for the establishment of the facility (if applicable) | Click here to enter the number of permit. |
| Name, email address and telephone number of the Hungarian contact person | Click here to enter text. |

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| **2. Information on the activity***This section should describe the project, host organisms, vectors and genetic materials which should be reasonably detailed but not exhaustive.* |
| 2.1. Description of the project and contained used activities including the methods to be used and the purpose of the genetic modification |
| Click here to enter text. |
| 2.2. Expected maximum titres and culture volumes |
| Click here to enter the quantity. |
| 2.3. Host organisms and hazard groups |
| Click here to enter text. |
| 2.4. Vector systems |
| Click here to enter text. |
| 2.5. Genetic inserts or materials or deletions (eg origins, nature of genetic modifications and intended or modified functions) |
| Click here to enter text. |

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| **3. Risk Assessment***This section contains the risk assessment, the elements of which require an examination of the potential adverse effects on human health and the environment.* *It should include a clear and explicit justification of any statements made about the risks with a logical* *explanation and any relevant evidence or references. The level of risk is estimated using the matrix given at the end of this form and then stating the risk as either:**Effectively zero, Low, Low / Medium, Medium or High.* |
| **3.1. Risks to human health** |
| 3.1.1. Characteristics of the host, virus or viral vector and any hazards associated with it |
| 3.1.1.1. Describe all hosts that will be used, including where relevant, bacterial hosts and packaging cell lines used to produce non-replicating viral particles |
| Click here to enter text. |
| 3.1.1.2. Is the viral vector disabled/ attenuated? If yes, please descibe. | [ ]  Yes | [ ]  No |
| Click here to enter text. |
| 3.1.1.3. Describe the origin of the virus, the mechanisms of attenuation, and its stability in both the parent viral vector and the recombinant vector |
| Click here to enter text. |
| 3.1.1.4. Indicate the probability of reversion to the wild type? |
| Click here to enter text. |
| 3.1.1.5. Is the virus or virus vector capable of replication?  | [ ]  Yes | [ ]  No |
| 3.1.1.5.1. If yes, please descibe the method used to detect the presence of the virus possibly capable of replication |
| Click here to enter text. |
| 3.1.1.5.2. If no, is there a risk of the virus regaining its replication capacity, especially in an industrial production process?  |
| Click here to enter text. |
| 3.1.1.5.3. In case of gene therapy, is there a risk of vector modification due to the presence of trans-complementing sequences in the cell?  |
| Click here to enter text. |
| 3.1.1.6. Is the virus or virus vector capable of integrating into the host genome?  | [ ]  Yes | [ ]  No |
| 3.1.1.7. Are all potential routes of transmission of the virus known, eg those that may occur during laboratory accident? | [ ]  Yes | [ ]  No |
| 3.1.1.8. If yes, will the routes of transmission deliver the virus or its products to tissues where it may be biologically active? |
| Click here to enter text. |
| 3.1.1.9. Does the viral vector infect humans or human cells *in vitro*? | [ ]  Yes | [ ]  No |
| 3.1.1.10. Is there a potential for the transmission of the naked nucleic acid? | [ ]  Yes | [ ]  No |
| 3.1.2. Source and characteristics of the inserted gene products and any hazards arising directly from their use |
| Click here to enter text. |
| 3.1.2.1. Describe the nature of the inserted genes and properties the final genetically modified viral vector, including the expression cassette (promoter, terminator and enhancer sequences), the structural genes, and the elements, if any, that are not involved in the expression of the intended trait |
| Click here to enter text. |
| 3.1.2.2. Does the insert code for a protein with known or suspected physiological, pathological and or pharmacological effect (eg toxins, carcinogens, allergens, virulence or immunomodulatory products?  | [ ]  Yes | [ ]  No |
| 3.1.2.3. Will the viral vector contain any natural or inserted oncogene and/or oncogenic sequences? | [ ]  Yes | [ ]  No |
| 3.1.3. Hazards arising from the alteration of any existing pathogenic traits |
| 3.1.3.1. Is there a reason to suspect that the host range of the recombinant virus will be any different from that of the parent vector or virus?  | [ ]  Yes | [ ]  No |
| 3.1.3.2. Is there a reason to suspect that the tissue tropism of the recombinant virus will be any different from that of the parent vector or virus? | [ ]  Yes | [ ]  No |
| 3.1.3.3. Is there a reason to suspect that the recombinant virus may have altered susceptibility to host defence mechanisms? | [ ]  Yes | [ ]  No |
| eg Will normal immune status be compromised by the recombinant virus? | [ ]  Yes | [ ]  No |
| eg Does the vaccine protect against the recombinant virus? | [ ]  Yes | [ ]  No |
| 3.1.3.4. Is the recombinant virus likely to have any effect upon an immunocompromised host beyond those normally expected with the parental virus? | [ ]  Yes | [ ]  No |
| 3.1.3.5. Will viral susceptibility to anti-viral drugs (if available) be affected by the genetic modification? | [ ]  Yes | [ ]  No |
| 3.1.3.6. Could the route of transmission of the recombinant virus be altered? | [ ]  Yes | [ ]  No |
| 3.1.3.7. If yes, what are the predicted effects of the recombinant viruses in tissues which it would not normally infect? |
| Click here to enter text. |
| 3.1.4. Potential hazard of harmful sequences within the virus being transferred to related viruses? |
| Click here to enter text. |
| 3.1.5. Does this work pose a specific risk to susceptible individuals such as immunocompromised people, pregnant women, new mothers, etc.? If so, please provide details below. | [ ]  Yes | [ ]  No |
| Click here to enter text. |
| 3.1.6. What is the likelihood that, in the event of exposure, the GM virus could cause harm to human health?  |
| Click here to enter text. |
| 3.1.7. Overall assessment of risk to human health based on the answers to questions 3.1.1 - 3.1.6. and using the matrix given at the end of this form |
| Level of risk (Select one) | [ ]  Effectively zero |
| [ ]  Low |
| [ ]  Medium/Low |
| [ ]  Medium |
| [ ]  High |
| **3.2. Risks to environment** |
| 3.2.1. What is the capacity of the GMM to survive and establish in the environment, disseminate with and or displace other organisms?  |
| 3.2.1.1. Is there a reason to suspect that the recombinant virus may have enhanced environment survival factors; eg enhanced tolerance to UV, temperature, desiccation etc? | [ ]  Yes | [ ]  No |
| Click here to enter text. |
| 3.2.1.2. Are potential routes of transmission or escape of the virus to the environment known eg following a laboratory accident? | [ ]  Yes | [ ]  No |
| 3.2.1.3. If yes, will the recombinant virus or its products gain access to organisms in which effects may be manifested? | [ ]  Yes | [ ]  No |
| Click here to enter text. |
| 3.2.2. What is its ability to cause harm to organisms other than humans? |
| 3.2.2.1. Is the host pathogenic to organisms other than humans? | [ ]  Yes | [ ]  No |
| Click here to enter text. |
| 3.2.2.2. Does the insert code for a protein with known or suspected inhibitory, detrimental, or other physiologically active effect on any organisms other than humans? | [ ]  Yes | [ ]  No |
| Click here to enter text. |
| 3.2.2.3. Is there a potential for harmful effects of gene expression on other organisms? | [ ]  Yes | [ ]  No |
| Click here to enter text. |
| 3.2.2.4. Will the recombinant virus alter infectivity or interactions with host defence mechanisms? | [ ]  Yes | [ ]  No |
| Click here to enter text. |
| 3.2.2.5. Will the normal status of host defence systems be compromised by the recombinant virus? | [ ]  Yes | [ ]  No |
| Click here to enter text. |
| 3.2.2.6. Is the recombinant virus likely to have enhanced effects on a weakened host or one lacking normal vigour beyond those normally expected with the parent virus? | [ ]  Yes | [ ]  No |
| Click here to enter text. |
| 3.2.2.7. Will viral susceptibility to control agents be affected by genetic modification? | [ ]  Yes | [ ]  No |
| Click here to enter text. |
| 3.2.2.8. Will the insert/modification/deletion cause changes in the host range of the virus? | [ ]  Yes | [ ]  No |
| Click here to enter text. |
| 3.2.2.9. Is there a reason to suspect that the tissue tropism of the recombinant virus in host organisms will be different from that of the unmodified virus? | [ ]  Yes | [ ]  No |
| Click here to enter text. |
| 3.2.3. What is the potential for transfer of genetic material between the GMV/GMVV and other organisms?  |
| Click here to enter text. |
| 3.2.4. Overall assessment of risk to environment based on the answers to questions 3.2.1 - 3.2.3. and using the matrix given at the end of this form |
| Level of risk (Select one) | [ ]  Effectively zero |
| [ ]  Low |
| [ ]  Medium/Low |
| [ ]  Medium |
| [ ]  High |
| **3.3. Risk classification for GMV/GMVV** |
|  Level of risk (Select one) | [ ]  1  | [ ]  3 |
| [ ]  2  | [ ]  4  |

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| **4. Control Measures to Eliminate or Reduce Risks of Exposure or Release***This section contains the minimum requirements and measures necessary for each level of containment.* *Containment is also achieved through the use of good work practices, training, containment equipment and special installation design.* |
| 4.1. Containment level (Select one) | [ ]  1  | [ ]  3 |
| [ ]  2  | [ ]  4 |
| 4.2. Containment laboratories or facilities |
| Select all that apply | [ ]  Laboratory  |
| [ ]  Animal facility |
| [ ]  Plant facility |
| [ ]  Other\* |
| \*Please specify: Click here to enter text. |
| 4.3. Microbiological safety cabinets and isolators |
| Select all that apply | [ ]  Class 1 |
| [ ]  Class 2 |
| [ ]  Class 3 |
| [ ]  Isolator |
| [ ]  Other\* |
| \* Please specify: Click here to enter text. |
| 4.4. Special controls |
| Click here to enter text. |
| 4.5. Personal protective equipment |
| Select all that apply | [ ]  Lab coat |
| [ ]  Lab gown |
| [ ]  Surgical scrubs |
| [ ]  Disposable clothing |
| [ ]  Apron |
| [ ]  Safety spectacles |
| [ ]  Face shield |
| [ ]  Gloves |
| [ ]  Headwear |
| [ ]  Footwear |
| [ ]  Other\* |
| \* Please specify: Click here to enter text. |
| 4.6. Respiratory protective equipment |
| Select all that apply | [ ]  Filter mask |
| [ ]  Half face respirator |
| [ ]  Full face respirator |
| [ ]  Powered respirator |
| [ ]  Breathing apparatus |
| [ ]  Other\* |
| \* Please specify: Click here to enter text. |
| 4.7. Storage controls  |
| Click here to enter text. |
| 4.8. Controls for on-site transport of the GMV/GMVV |
| Click here to enter text. |
| 4.9. Inactivation controls of the GMV/GMVV |
| Select all that apply | [ ]  Disinfection |
| [ ]  Autoclave |
| [ ]  Fumigation |
| [ ]  Incineration |
| [ ]  Other\* |
| \* Please specify: Click here to enter text. |
| 4.10. Waste disposal routes |
| Click here to enter text. |
| 4.11. Immunisations (if applicable) |
| Click here to enter text. |
| 4.12. Instructions, training and supervision |
| Click here to enter text. |
| 4.13. Import, export or other licence of the GMA (if applicable) |
| Click here to enter text. |

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| **5. Emergency Procedures***This section should describe an emergency plan which is drawn up for contained uses where failure of the containment measures could lead to serious danger, whether immediate or delayed, to humans outside the premises and/or to the environment.* |
| 5.1. Description of the emergency procedures |
| Click here to enter text. |
| 5.2. Emergency contact(s) |
| Name | Position | Telephone |
| Click here to enter text. | Click here to enter text. | Click here to enter text. |

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| **6. Approval***This section should be signed and dated both by the assessor and the principal investigator (who is responsible for the activity).* |
| 6.1. Risk assessor |
| Name | Signature | Date |
| Click here to enter text. |  | Click here to enter date. |
| 6.2. Principal investigator |
| Name | Signature | Date |
| Click here to enter text. |  | Click here to enter date. |
| *As the principal investigator for this project you have a legal responsibility to ensure that all those involved or working on the project have an appropriate level of training and expertise to enable safe working. This includes ensuring that workers read and understand this risk assessment and that all the control measures are in strict accordance with those approved for the project.* |

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| **7. Review***The risk assessment must be reviewed periodically, at least annually, and immediately if there are any significant changes to the work or where the risk assessment is no longer valid.* |
| 7.1. Risk assessor |
| Name | Signature | Date |
| Click here to enter text. |  | Click here to enter date. |
| 7.2. Principal investigator |
| Name | Signature | Date |
| Click here to enter text. |  | Click here to enter date. |

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| **Risk estimation matrix** |
| **Consequence of****hazard** | **Likelihood of hazard** |
| **High** | **Medium** | **Low** | **Negligible** |
| **Severe** | High | High | Medium | Effectively zero |
| **Modest** | High | Medium | Medium / Low | Effectively zero |
| **Minor** | Medium / Low | Low | Low | Effectively zero |
| **Negligible** | Effectively zero | Effectively zero | Effectively zero | Effectively zero |