# GM Risk Assessment Form 2: Genetically Modified Viruses and Virus Vectors

A GM risk assessment is required for any work involving the possession or use of genetically modified viruses and virus vectors and related materials. Please complete this form and email it to your GM Biological Safety Officer (GMBSO) to submit it to your GM Biological Safety Committee (GMBSC). The School GMBSO provides advice to Principal Investigators on GM risk assessment and HSE notification. You should read the guidance provided on GM risk assessment and biological safety on the Biosafety Unit website. Please complete the boxes that apply to your work.

## Section 1 Basic Details

| | |
|---|---|
| **Title of project** | |
| **Local reference number** | |
| **HSE reference number** | |
| **Principal investigator** | |
| **School / Institute** | |
| **Date of application** | |
| **Location of work** (Building and room numbers) | |

## Section 2 Project

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 activities including the methods to be used and the purpose of the genetic modification**

**2.2: Expected maximum titres and culture volumes**

**2.3: Host organisms and hazard groups**

**2.4: Vector systems**

**2.5: Genetic inserts or materials (eg origins, nature of genetic modifications and intended functions)**

## Section 3 Risk Assessment

This section should describe any potential risks to humans and or 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**

| | |
|---|---|
| **3.1.1.2: Is the viral vector disabled / attenuated** | Yes / No |

**3.1.1.3: Describe the origin of the virus, the mechanism of attenuation, and its stability in both the parent viral vector and the recombinant vector**

**3.1.1.4: Indicate the probability of reversion to the wild type**

| | |
|---|---|
| **3.1.1.5: Is the virus or viral vector replication competent** | Yes / No |
| **3.1.1.6: Are all potential routes of transmission of the virus known, eg those that may occur during a laboratory accident** | Yes / No |

**3.1.1.7: If Yes, will the routes of transmission deliver the virus or its products to tissues where it may be biologically active**

| | |
|---|---|
| **3.1.1.8: Is there a potential for the transmission of the naked nucleic acid** | Yes / No |
| **3.1.1.9: Does the viral vector infect humans or human cells *in vitro*** | Yes / No |

**3.1.2: Source and characteristics of the inserted gene products and any hazards arising directly from their use**

**3.1.2.1: Describe the nature of the inserted genes and the properties of the final genetically modified viral vector**

| | |
|---|---|
| **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 reason to suspect that the tissue tropism or 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 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 Will vaccination protect against the recombinant virus | Yes / No |

| | |
|---|---|
| **3.1.3.3: Is the recombinant virus likely to have any effect upon an immunocompromised host beyond those normally expected with the parental virus** | Yes / No |
| **3.1.3.4: Will viral susceptibility to anti-viral drugs (if available) be affected by the genetic modification** | Yes / No |
| **3.1.3.5: Could the route of transmission of the recombinant virus be altered** | Yes / No |
| **3.1.3.6: If Yes, what are the predicted effects of the recombinant viruses in tissues which it would not normally infect** | |
| | |
| **3.1.4: Potential hazard of harmful sequences within the virus being transferred to related viruses** | |
| | |
| **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** |
| | |
| **3.1.6: The overall likelihood that, in the event of exposure, the GM virus could cause harm to human health** | |
| | |
| **3.1.7: Overall assessment of risk to human health** (Prior to use of controls) | |
| **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, establish, disseminate with and or displace other organisms** | |
| **3.2.1.1: Is there reason to suspect that the recombinant virus may have enhanced environmental survival factors; eg enhanced tolerance to UV, temperature, desiccation etc** | Yes / No |
| | |
| **3.2.1.2: Are all 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 |
| | |
| **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 |
| | |

| | |
|---|---|
| **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 |
| | |
| **3.2.2.3: Is there a potential for harmful effects of gene expression on other organisms** | Yes / No |
| | |
| **3.2.2.4: Will the recombinant virus alter infectivity or interactions with host defence mechanisms** | Yes / No |
| | |
| **3.2.2.5: Will the normal status of host defence systems be compromised by the recombinant virus** | Yes / No |
| | |
| **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 |
| | |
| **3.2.2.7: Will viral susceptibility to control agents be affected by genetic modification** | Yes / No |
| | |
| **3.2.2.8: Will the insert cause changes in the host range of the virus** | Yes / No |
| | |
| **3.2.2.9: Is there 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 |
| | |
| **3.2.3: What is the potential for transfer of genetic material between the GMM and other organisms** | |
| | |
| **3.2.4: Overall assessment of risk to environment** (Prior to use of controls) | |
| **Level of risk** (Select one) | Effectively zero / Low / Medium/Low / Medium / High |
| **3.3 Risk classification for GM microorganisms** | |
| **3.3.1 Assign the risk class** (Select one) | 1 / 2 / 3 |

## Section 4 Control Measures to Eliminate or Reduce Risks of Exposure or Release

This section should describe the types of controls which will be required to carry out the work safely. You must follow the hierarchy of risk control by choosing the most effective control measures needed to safely carry out your work and not just the easiest controls. Please do not include detailed standard operating procedures which should be specified in a separate document.

| **4.1: Containment level** (Select one) | 1 / 2 / 3 |
|---|---|

| **4.2: Containment laboratories or facilities** | |
|---|---|
| Select all that apply | Laboratory / Animal facility / Plant facility / Other |

| **4.3: Microbiological safety cabinets (MSC) and isolators** | |
|---|---|
| Select all that apply | Class I / Class II / Class III / Isolator / Other |

**4.4: Sharps controls**

**4.5: Special controls**

| **4.6: Personal protective equipment (PPE)** | |
|---|---|
| Select all that apply | Lab coat / Lab gown / Surgical scrubs / Disposable clothing / Apron / Safety spectacles / Goggles / Face shield / Gloves / Headwear / Footwear / Other |

| **4.7: Respiratory protective equipment (RPE)** | |
|---|---|
| Select all that apply | Filter mask / Half face respirator / Full face respirator / Powered respirator / Breathing apparatus / Other |

**4.8: Storage controls**

**4.9: Transport controls**

| **4.10: Inactivation controls** | |
|---|---|
| Select all that apply | Disinfection / Autoclave / Fumigation / Incineration / Other |

**Disinfection**
Please give details of disinfectant(s), method and validation including concentration of disinfectant and contact time (eg supplier's instructions or local validation).

**Autoclaving**
Please give details of autoclave method and validation.

All contaminated materials will be inactivated by autoclaving (100% kill) at 121°C or 134°C prior to disposal of waste or cleaning and recycling of reusable laboratory equipment, such as glassware. Autoclaves will be validated by annual (at least) thermocouple mapping and each run will be monitored by continuous chart or digital recording of the temperature / time profile.

Or

All contaminated materials will be inactivated by autoclaving (100% kill) at 121°C or 134°C prior to disposal of waste or cleaning and recycling of reusable laboratory equipment, such as glassware. Autoclaves will be validated by annual (at least) thermocouple mapping and each run will be monitored using chemical indicators (eg Browne TST indicator test strips).

**Other**
(Please give details of method and validation).

**4.11: Waste disposal routes**

**4.12: Immunisations (if applicable)**

**4.13: Instructions, training and supervision**

**4.14: HSE notification (if applicable)**

**4.15: Specified Animal Pathogen Order (SAPO) licence (if applicable)**

**4.16: Plant Health Order (PHO) licence (if applicable)**

**4.17: Import, export or other licence (if applicable)**

## Section 5 Emergency Procedures

This section should describe any emergency procedures used to deal with accidental exposure, release or spillages.

**5.1:Emergency procedures**

**5.2:Emergency contacts**

| Name | Position | Telephone |
|---|---|---|
| | Principal Investigator | |
| | | |

## Section 6 Emergency Planning

This section should describe any emergency plan used to deal with serious accidental release. An emergency plan is only required for high risk work.

| **6.1: Emergency plan required in case of serious accidental release to protect humans or environment** | Yes / No |
|---|---|
| | |

## Section 7 Approval

This section should be signed and dated by the assessor, principal investigator and GMBSO.

**7.1: Assessor**

| Name | Signature | Date |
|---|---|---|
| | | |

**7.2: Principal investigator**

| Name | Signature | 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. You should also check for compliance with the control measures.

**7.3: School GMBSO Biological Safety Adviser for GMBSC**

| Name | Signature | Date |
|---|---|---|
| | | |

## Section 8 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.

**8.1: Assessor**

| Name | Signature | Date |
|---|---|---|
| | | |

**8.2: Principal investigator**

| Name | Signature | Date |
|---|---|---|
| | | |

## 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 |