**Risk Assessment for Biological Activity (GM and BioCOSHH Assessment)**

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| **Project Reference*: This is assigned locally*** |

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| **A: PROJECT OVERVIEW** |
| **Applicant:**  | **Date:**  |
| **Project Title:**  |
| **Name of project leader:**  | **Organisation:**  |
| **Contact details:**  |
| **Personnel involved in the project:**  |
| **Briefly (maximum 500 words) describe the activity to be undertaken, including the aim of the work (Explain what you are proposing to complete e.g summary of protocols):**  |
| **List all the locations of the proposed activity:**  |
| **Is any of the material listed under the following regulations:**SAPO (Specified Animal Pathogens Order) Yes [ ]  No [ ] Schedule 5 (Anti-Terrorism Crime and Security Act) Yes [ ]  No [ ] HTA (Human Tissue Act) Yes [ ]  No [ ] Imported material (directly here from outside UK-APHA)Yes [ ]  No [ ]  |

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| **DOES THIS WORK INVOLVE (Select one option only)** |
| 1. **Biological Non- GM activity only**

  If yes, please complete sections B and D | Yes [ ]  |
| 1. **Biological GM activity only**

  If yes, please complete sections C and D | Yes [ ]  |
| 1. **Both biological GM activity and Non GM activity**

 If yes, please complete sections B, C and D  | Yes [ ]  |

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| **B: Project Risk Assessment involving Biological Non - GM activity** *Give justification for all answers- e.g. N/A or No are not acceptable without justification.* |
| **The nature of the biological material**  |
| 1. **Describe the biological materials involved in the activity**
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| 1. **Describe how and from where the materials will be obtained.**
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| 1. **Explain any pre-treatments that will reduce risk (e.g. fixation/inactivation etc)**
 |
| 1. **Where will the biological materials be stored (short and long term)?**

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| 1. **How will the materials be stored (e.g. frozen, refrigerated, liquid nitrogen)?**
 |
| **Risks from biological material and biological agents present in the material** |
| 1. **Describe the risks associated with biological agent(s) or toxins likely to be present in the biological material**
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| 1. **Provide information on the mode of transmission, disease caused and symptoms. If any toxins present, please provide information on its likely concentration in the material and at what level it** **has an effect on human health.**
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| 1. **Provide information on the likely viability of the biological material and any biological agents present in it.**
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| 1. **Provide information on any risks posed to the environment, e.g., ability to survive outside the laboratory, effects on the ecosystem.**
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| 1. **Does the biological material or biological agent(s) present appear on the ACDP Approved List of Biological Agents and, if so, what is its hazard group under COSHH?**

**If the biological material or biological agent(s) has not been assigned a hazard group, what is your provisional classification, based on existing knowledge of its ability to cause disease, spread in the community etc?** |

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| **C: PROJECT RISK ASSESSMENT INVOLVING BIOLOGICAL GM ACTIVITY ONLY.** *Give justification for all answers- e.g. N/A or No are not acceptable without justification.* |
| **Describe the individual elements of the GMOs to be constructed or used**  |
| 1. **Recipient organism(s)**
2. **Genetic alterations made (e.g. sequences expressed)**
3. **Vector sequences incorporated into the final GMO**
 |
| **Consideration of potential properties of the GMM/GMO to determine if there are any potential mechanisms by which it could present a hazard to human health and/or the environment.** |
| **i) Hazards associated with the recipient micro-organism** (e.g. ACDP and SAPO classification, transmission, host range etc)1. **Human:**
2. **Environmental:**
 |
| **ii) Hazards arising directly from the inserted genetic material** (e.g. does it code for a toxin, an oncogenic protein or anything which could cause harmful biological activity)1. **Human:**
2. **Environmental:**
 |
| **iii) Hazards arising from the alteration of existing pathogenic traits** (e.g. alteration of host range or tissue tropism)1. **Human:**
2. **Environmental:**
 |
| **iv) Potential risk of sequences within the GMM/GMO being transferred to related micro-organisms** (e.g. via gene transfer or recombination, survivability in the environment)1. **Human:**
2. **Environmental:**
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| **Briefly describe the GMOs to be used/constructed (if not known, *predict it*)** |
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| **Assignment of provisional Containment Level to protect human health.** (This is based on the information provided in all the answers given above) | Containment Level 1 (CL1)  | [ ]  |
| Containment Level 2 (CL2) [ ]   | [ ]  |
| Greater than CL2 [ ]  | [ ]  |
| **Assignment of provisional Containment Level to protect against harm to the environment.** (This is based on the information provided in all the answers given above) | Containment Level 1 (CL1) [ ]  | [ ]  |
| Containment Level 2 (CL2) [ ]  | [ ]  |
| Greater than CL2  | [ ]  |

**D: Control measures**

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| **D: Control Measures** |
| **Where relevant, and based on the hazards identified above, please describe the control measures needed to reduce the risk of harm to human health and the environment.**  |
| 1. **Risk of inhalation or escape via the air (aerosols)**
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| 1. **Risk of sharps injury**
 |
| 1. **Risk from direct contact and/or vectoring (contaminated surfaces, equipment, and objects)**
 |
| 1. **Any other required control measures (training, restricted access, procedures etc)**
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| 1. **Describe how waste will be collected, treated and disposed of**
	1. **Solid waste**
	2. **Liquid waste**
 |
| 1. **Describe how spills will be dealt with in each location**
 |
| 1. **Describe how materials will be transported**
	1. **Nationally and internationally**
	2. **Between buildings and identified locations**
	3. **Within the laboratory**
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| 1. **Any other information (e.g. COSHH assessment for chemicals involved)**
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| **Assignment of the proposed GM activity class** | Class 1  | [ ]  |
| Class 2  | [ ]  |
| Greater than Class 2  | [ ]  |

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| **E: Documentation, Licences & Approvals** |
| 1. List and attach any supporting documentation (include COSHH assessments if required).
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| 1. Does the above proposed work require any licences, notifications and approvals?

 Yes [ ]  No [ ]  Not sure, seek further advice [ ] If yes, what are they? Please give details of approved licences available or give details of any outstanding applications submitted to the concerned authority. |

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| **F: SIGNATURES AND REVIEW** |
| **Person responsible for project** | **Signature:**  |
| **Date:**  | **Name:**  |
| **Person completing risk assessment** (if different from above) | **Signature:**  |
| **Date:**  | **Name:**  |
| **BSO/GMSMC member** (Required for all) | **Signature:**  |
| **Date:**  | **Name:**  |
| **GMSMC Chair** (Only required for CL2 or Class 2) | **Signature:**  |
| **Date:**  | **Name:**  |

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| **For completion by the Institute’s GMSMC representative**  |
| **Final Assignment of biological activity level:**  |
| **GMSMC comments:** |
| **HSE approval needed:**  | **HSE approval granted:** |
| **Appendix in place:** | **Amendment in place:** |
| **Proposal Approved/Rejected** |
| **Date:** |

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| **ROUTINE REVIEW**Reviews completed with minor changes or no changes can be recorded below. Minor changes include those that do not change the risk (e.g. administration changes)**A new version of the assessment MUST be submitted if there are major changes that change the risk.** |

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| **Comments:** *Specify all changes made – if no changes made specify this* |
| **Review Date:** |  | **Person Responsible for project:** *(Signature)* |  |
| **BSO/GMSMC Member:** |  | **GMSMC Chair:** *(Only required for non administrive changes in CL2 or GM Class 2 assessments)* |  |