**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** |
| 1. **Describe how and from where the materials will be obtained.** |
| 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)?** |
| 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** |
| 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.** |
| 1. **Provide information on the likely viability of the biological material and any biological agents present in it.** |
| 1. **Provide information on any risks posed to the environment, e.g., ability to survive outside the laboratory, effects on the ecosystem.** |
| 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:** |
| **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)** |
| 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)** |
| 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** |
| 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). |
| 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)* |  |