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| **Advanced Therapies Gene Modification Safety Committee**  **Approved Clinical Risk Assessment Report** |

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| **ATMP Details** | | | | | |
| Type of ATMP |  | | Clinical Trial or Medicine? | |  |
| ATMP title |  | | | | |
| Lead Clinician or PI: |  | | | | |
| Planned start date at site: |  | | Planned end date at site: | |  |
| NHS Lothian Location(s): |  | | | | |
| **Approvals in Place:** |  |  | |  | |

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| **ATGMSC Review Details** | | | |
| **RA Report**  **Version and Date** |  | | |
| **Lead Reviewer** |  | | |
| **Contributing Committee Members** |  | | |
| **Date of Committee review** |  | | |
| **Regulatory Approvals (Clinical trials)** | **Are there conditions to approval? MHRA**: Yes/No **REC:** Yes/No  **Do these conditions impact on risk and safety in relation to the ATMP?** | | |
| **Documents reviewed by ATGMSC** | **Initial Review (pre ATGMSC approval)** | **Amendments** | |
| **Comments** |  | | |
| **ATGMSC Decision** |  | **Date** |  |

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| **Risk Assessment Report of ATMP to be used in NHS Lothian Clinical Areas** | |
|  | **Committee Comments** |
| **Advanced Therapy Medicinal Product Details** |  |
| Type of ATMP  Clinical Trial or Medicine? |  |
| **Section 1: Application Details** |  |
| **1.1a Study Details (Clinical Trials)** |  |
| **1.1b (ATMP details) – licensed or unlicensed medicines** |  |
| 1.2 Principal Investigator  1.3 Role of PI  1.4 PI Mentor  1.5 Main Study Contact  1.6 Pharmacy Contact |  |
| **Section 2: Approvals, Consents, Notifications and Licences** |  |
| **Section 3: Lay Summary of Research** |  |
| **Section 4: Scientific Detail of the Research** |  |
| **Section 5: Details of the GM(O) Products** |  |
| 5.1 – Full Description of the Host Microorganisms  5.2 – Full Description of the Vector(s)  5.3 – Full List and Description of the Inserts(s)  5.4 – In vitro use of the GMO  5.5 – In vivo use of the GMO |  |
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| **Section 6: Risks to Human Health** |  |
| 6.1 – Unaltered Host Organisms/Vectors  6.2 – Inserts  6.3 – Modified Host Organisms/Vectors  6.4 – Recombination  6.5 – Hazards to Human Health  6.6 – Assessment of Risk  6.7 – Interim Assignment of GM Class (Human Health) |  |
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| **Section 7: Risk to the Environment** |  |
| 7.1 – Unaltered Host Organisms/Vectors  7.2 – Inserts  7.3 – Modified Host Organisms/Vectors  7.4 – Recombination  7.5 – Environmental Hazards  7.6 – Likelihood of Release  7.7 – Contained Use or Deliberate Release  7.8 – Assessment of Risk  7.9 – Interim Assignment of GM Class (Environmental Risk) |  |
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| **Section 8: Final Assignment of GM Class and Containment Level** |  |
| **Section 9: Occupational Health** |  |
| 9.1 – Health Effects  9.2 – Medical Risk Assessment  9.3 – Pre-Exposure Arrangements  9.4 – Post-Exposure Action  9.5 – Antibiotic Treatment or Chemoprophylaxis  9.6 – Health Surveillance Required  9.7 – Additional Notes & Comments |  |
| **Arrangements to Control Risk** |  |
| **Section 10: Patient Considerations** |  |
| 10.1 - Administration to Patient |  |
| 10.2 - Patient Care |  |
| 10.3 - Patient Follow up |  |
| **Section 11: Staff Considerations** |  |
| 11.1 Staff Safety and Surveillance |  |
| **Section 12: Waste Management Considerations** |  |
| 12.1 – Waste Management |  |

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| **Section 13: Pharmacy and Product Preparation/Storage and Transport** |  |
| 13.1 – Manufacture |  |
| 13.2 – Shipment/GMP receipt |  |
| 13.3 – Storage |  |
| 13.4 – Preparation / Manipulation |  |
| 13.5 – Transfer to Administration Area |  |
| 13.6 – Chain of custody |  |
| 13.7 – Prescription |  |
| 13.8 - Disposal |  |
| **Section 14: Information, Instruction, Supervision and Training** |  |
| 14.1 – Relevant SOPs  14.2 - Training |  |
| **Section 15: Accommodation** |  |
| **Section 16: Personnel at risk** |  |
| **Section 17: Declarations and Approvals** |  |
| **Additional Committee Comments** |  |
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| **Summary of Changes from Version X to Version Y of Risk Assessment Report** | | |
| Section | Summary of Change | Reason for Change |
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| **Approvals and Signatures** |
| **This study has been risk assessed by the ATGM Safety Committee and approved to proceed within NHS Lothian Clinical Areas mentioned.**  **The Risk Assessment Report is approved by the signatories below following ATGMSC review of the Risk Assessment and accompanying documents. Subsequent amendments to these documents, or any other changes that may affect this risk assessment, must be submitted to the ATGMSC for review and approval.**  **Any amendments that affect the information in this report will result in the issue of a new version. Any other amendments may require a letter of approval from the ATGMSC but no update to this report.**  **Signature of PI/Clinician: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** **Date:**  **Signature of Chair: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:**  **Signature of BSO: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:** |