**Biohazard Risk Assessment**

To be completed prior to acceptance of any deposit into a NIBSC depositary

**SECTION 1: To be completed by the depositor (please complete all boxes)**

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| 1. **Type of cell line:** (you may tick more than one box)

Animal Cell Line [ ]  Human Cell Line [ ]  Embryonic Stem Cell Line [ ] 1. **Genetically modified:**

 Yes [ ]  No [ ]  If yes, what Class  |

If the **YES** box is checked also complete section 2. If you have indicated Class 2 or above please forward any risk assessment you have undertaken relating to this cell line

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| 1. **Cell / cell line name or ID code:**

      | 1. **Species:**

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| 1. **ACDP hazard group1:**

Group 1: [ ]  2: [ ]  3: [ ]  4: [ ]  (if USA deposit, use SALS Categories) |

1Advisory Committee on Dangerous Pathogens

Hazard Group 1: A biological agent unlikely to cause human disease.

Hazard Group 2: A biological agent that can cause human disease and may be a hazard to employees. It is unlikely to spread to the community and there is usually effective prophylaxis and effective treatment available.

Hazard Group 3: A biological agent that can cause severe human disease and presents a serious hazard to employees. It may present a risk of spreading to the community, but there may be prophylaxis or treatment available.

Hazard Group 4: A biological agent that causes severe human disease and is a serious hazard to employees. It is likely to spread to the community and there is usually no effective prophylaxis or treatment available.

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| 1. **Does this deposit require a specified animal pathogen order:**

Yes [ ]  No [ ]  (If yes please refer to the DEFRA website [www.defra.gov.uk](http://www.defra.gov.uk) for a licence application) |

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| 1. **Sterility checks carried out by depositor on cell deposit**

(Check boxes below. If any **Yes** box is checked, please also check boxes on the right)Mycoplasma Yes [ ]  No [ ]  Positive [ ]  Negative [ ] Bacteria Yes [ ]  No [ ]  Positive [ ]  Negative [ ] Fungi Yes [ ]  No [ ]  Positive [ ]  Negative [ ]  |

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| 1. **Viral tests conducted by depositor on cell line or donor** (Only applies to cells of human origin)

(Check boxes below. If any **Yes** box is checked, please also check boxes on the right. If you do not know whether the original tissue/cell donor or the cell line was tested, please check the **No** box.)HIV 1/2 Yes [ ]  No [ ]  Positive [ ]  Negative [ ] HBV Yes [ ]  No [ ]  Positive [ ]  Negative [ ] HCV Yes [ ]  No [ ]  Positive [ ]  Negative [ ] HTLV 1/2 Yes [ ]  No [ ]  Positive [ ]  Negative [ ] Other (please specify)       Yes [ ]  No [ ]  Positive [ ]  Negative [ ]  |

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| 1. **Details of positive results** (If the “Positive” check box in questions 8 or 9 has been checked please provide further details)

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| 1. **Brief description of deposit** (If the cell is genetically modified include details of inserted gene, method/vehicle for insertion and any expression product)

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**Section 2:** **To be completed by the depositor if the deposit is genetically modified**

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| 1. **ACDP hazard group1:**

 Group 1: [ ]  2: [ ]  3: [ ]  4: [ ] 1. **Does the GM agent contain/produce a biologically active substance that could potentially cause harm to humans**

 Yes [ ]  No [ ] 1. **What is the likelihood that the genetic modification can confer pathogenic traits in the host organism**

 Negligible: [ ]  Possible: [ ]  Probable: [ ]  Demonstrated: [ ] 1. **What is the potential for sequences within the GM organism being transferred to another related organism**

 Negligible: [ ]  Low: [ ]  Medium: [ ]  High: [ ] 1. **In the event of exposure, what is your assessment of the potential of this GM organism to cause harm to human health**

 Negligible: [ ]  Low: [ ]  Medium: [ ]  High: [ ]  |

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| 1. **Additional Information** (If the **YES** check box in Section 2B was checked or any check box other than the “Negligible” box was checked in to Sections 2C, 2D or 2E please supply additional information)

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**Section 3:** **Form completed by:**

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| Name of Depositor:      | Date:      | Signature: |
| E-mail:      | Tel:      | Fax:      |

**Section 4:** **To be completed by NIBSC**

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| Authorised for deposit by:      | Date:      | Signature: |
| NIBSC RA Reference Number:      | Date Issued:      | Issue by:      |