**PROPOSAL FORM FOR ASSESSMENT OF GENETIC MANIPULATION WORK**

GMAC Ref No.:

(For official use only)

**Name of Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Name of Institution : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Experiment Risk Group (please check the appropriate box):**

Category A Category B Category C

**A. Experimental detail** (attach separate sheet if necessary)

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| 1. Project title (Please provide reference numbers for projects with the same title.) |
| 2. Research unit involved |
| 3. Experimental objective |
| 4. Rationale for the experiment |

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| 5. Scope of experiment – involvement of  Microorganisms and/or viruses  Toxins  Animals    Cells  Others, please specify: \_\_\_\_\_\_\_\_\_\_\_  Note: For experiments that involve animals, cells and/or others, please proceed to 6 and the rest, but skip 7 & 8. For experiments that involve microorganisms, viruses and/or toxins, please skip 6 and proceed to the rest of the form. For experiments that involve multiple experimental organisms (i.e. animals/cells together with microorganisms/viruses/toxins), please proceed to fill up all relevant questions. For experiments that involve HIV-based lentiviral vectors, please also fill up the table in Appendix I. |
| **6. Project with experiment involving animals/cells/others**  a. Can the modification result in a predictable change of the following:  i) Increased oncogenicity:  Yes  No  ii) Potential to change natural microbiome/ecology of the organism:  Yes  No    Details, if “yes”:  b. Description of gene(s) involved, gene construct(s) and intended experimental host system.  c. Method of gene delivery (bacteriophage, vectors, breeding, injection, biological delivery vehicle/carrier etc.) |
| **7. Project with experiment involving microorganisms/viruses/toxins**  a. Name of microorganism/virus/toxin: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  b. Is the microorganism/virus/toxin listed under the BATA List of Biological Agents and Toxins, and/or a potential human pathogen?   * 1. If Yes, provide the BATA Schedule: \_\_\_\_\_\_\_\_\_\_\_\_\_\_   2. If No, provide the risk grouping (for biological agent): \_\_\_\_\_\_\_\_\_\_     c. Brief description of gene modification on the microorganism/virus:   1. Gene(s) involved and gene construct(s) and intended experimental host system *(if chimeric microorganism is created, please specify the backbone and the inserted genes)*: \_\_ 2. Natural host of microorganism/virus: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 3. Method of gene delivery (transformation, conjugation, vectors, breeding, injection, biological delivery vehicle/carrier etc. For retroviral vectors, please specify the (viral) origin, and also note all safety features included in the constructs. For HIV-based lentiviral vectors, please specify the BATA Schedule of HIV lentiviral vectors): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
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| **8. For dual use research of concern (DURC)**  *(This section is to screen for DURC relating to research work involving GMOs- microorganisms/viruses/toxins. Kindly fill up the following questions to the best of your abilities.)*  Is there a reasonable possibility that the modification might result in a change of the following?  *(If unsure, choose “Yes” and explain under Details).*   * + 1. Increase in host range:   Yes  No   * + 1. Increased virulence:   Yes  No   * + 1. Immunogenicity:   Yes  No   * + 1. Increased toxicity:   Yes  No   * + 1. Increased transmissibility/ability to disseminate:   Yes  No   * + 1. Increased drug resistance:   Yes  No   * + 1. Enhanced susceptibility of host population:   Yes  No   * + 1. Increased stability:   Yes  No   * + 1. Potential to change natural microbiome/ecology of the organism:   Yes  No  Details, if “yes” to any of the above:  *(e.g. if the resultant product has increased drug resistance, please provide info on the extent of the resistance, and if there is still effective drug or treatment for infected individuals)* |
| 9. Duration of the experiment  1 year  2 years  3 years |
| 10. The proposed work will be performed in the following biocontainment level:  BSL1/ABSL1  BSL2/ABSL2  BSL2+/ABSL2+  BSL3/ABSL3 |
| 11. Measures to ensure containment, safe handling, storage and disposal |
| 12. For organism/microorganism  a. Experimental GMO Material to be obtained from (please note requirements for import permit for importation of biological agents and/or toxins regulated under the BATA):  b. Anticipated date of transfer or receipt: |
| 13. PI’s declaration:    I declare that the above information is accurate and complete based on risk assessment, and to the best of my knowledge.  I recognise that the actual risk may defer from the assessed risk. I will continue to monitor the risk of the project and the genetically modified organism. Should the risk assessment change with respect to 8 and/or 10, I will stop work immediately and notify the IBC, which will then notify MOH and GMAC. |

**Submitted by PI:**

**PI’s Name and Signature Appointment / Laboratory Date**

**Contact Details**

Address :

Business Tel Number : Fax Number :

Business Email :

**Reviewed by IBC:**

**IBC Chairman’s Name and Signature Date**

**The following section is applicable for Category A experiments only:**

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| Please indicate if approval has been sought from relevant regulatory authority (MOH/NEA/NParks) for \*use/possession/import/transport of the GMO.  If yes, please provide copy of document or reference.  If no, please explain why.  *\*(highlight where applicable)*  *For a list of regulatory contact points, please refer to Section 6.6 and 6.7 (page 26-28).* |

**Appendix I**

Please complete the table below to assess if the HIV-based lentiviral vector system (HIV LVS) used suffices the revised criteria of HIV LVS under the BATA Fourth Schedule.

A HIV LVS that possesses at least 2 of the following features is classified under the Fourth Schedule of the BATA:

1. the U3 region of the 3’LTR in the transfer vector is absent or altered, which results in a stable self-inactivating (SIN) configuration;
2. the HIV genes for packaging function are splitto a minimum of 2 packaging plasmids(excluding the env plasmid);
3. the vpr, vpu, vif and nef genes are either absentor altered to be non-functional; and
4. the vector system requires minimally4-recombination to achieve ReplicationCompetent Lentivirus (RCL)

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| --- | --- | --- | --- | --- |
| **S/N** | **HIV-based Lentiviral Vector System**  **(include vector names)** | **Features incorporated in vector system** | **Supporting Documents** | **Suffice HIV LVS criteria regulated under BATA Fourth Schedule** |
| 1 | Example-  XXX Vector System  Transfer vector – ABC plasmid  Packaging vector 1 – 123 plasmid  Envelope vector – XYZ  plasmid | Feature I  Feature III | Attachments | Y |
| 2 | Example-  BBB Vector System  Transfer vector – XYZ plasmid  Packaging vector 1 – 456 plasmid  Envelope vector – RST plasmid | Feature I only | NA | N |
|  |  |  |  |  |