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)

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

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?
   i) If Yes, provide the BATA Schedule: _____
   ii) If No, provide the risk grouping (for biological agent): _____

c. Brief description of gene modification on the microorganism/virus:

   i) 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)*: __

   ii) Natural host of microorganism/virus: _____

   iii) 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): _____

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).

i) Increase in host range:
☐Yes
☐No
ii) Increased virulence:
☐Yes
☐No
iii) Immunogenicity:
☐Yes
☐No
iv) Increased toxicity:
☐Yes
☐No
v) Increased transmissibility/ability to disseminate:
☐Yes
☐No
vi) Increased drug resistance:
☐Yes
☐No
vii) Enhanced susceptibility of host population:
☐Yes
☐No
viii) Increased stability:
☐Yes
☐No
ix) 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**

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The following section is applicable for Category A experiments only:

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:

I. the U3 region of the 3'LTR in the transfer vector is absent or altered, which results in a stable self-inactivating (SIN) configuration;
II. the HIV genes for packaging function are split to a minimum of 2 packaging plasmids (excluding the env plasmid);
III. the vpr, vpu, vif and nef genes are either absent or altered to be non-functional; and
IV. the vector system requires minimally 4-recombination to achieve Replication Competent Lentivirus (RCL)

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