UNIVERSITY OF HONG KONG

For use by the Biosafety Committee
Application Number:-

Form RA3

RISK ASSESSMENT FOR AN ACTIVITY INVOLVING DELIBERATE WORK WITH RECOMBINANT RETROVIRUSES INCLUDING LENTIVIRAL VECTOR EXPRESSION SYSTEMS

The following is a pilot version of a risk assessment form for work with recombinant retroviruses. The form is intended to help identify appropriate safe working practices. Please expand boxes and add lines etc as required.

The risk assessment form is divided into two parts an administrative section and the assessment part.

The aim is to take the scientist proposing the work through the process in a logical and systematic way. It is hoped that the structure provided within the format itself will assist researchers in organising their thought processes and that it will indicate to them those aspects of specific types of work which need to be given particular attention. Specific worked examples are also provided on the safety office website.

As it stands the form is primarily aimed at risk assessments where human health and the prevention of unintentional infection is the main concern. The form may need modification or expansion before it would be totally suitable for infectious work where environmental issues are the primary concern or where a large proportion of the work involved say gene therapy or the use of transgenic animals/plants.

PART 1 ADMINISTRATIVE DETAIL

Review History			
	Review 1	Review 2	Review 3
Due Date of Review			
Date Carried out			
Carried out by (initials)			

1. PERSON/S RESPONSIBLE FOR THIS WORK (PRINCIPAL INVESTIGATOR)	
Name:	Position:
Faculty:	Department:

2. OTHER STAFF INVOLVED					
Name	Position and Experience	Faculty	Department	Start date	Finish date (when known)

3. PERSON CARRYING OUT THE RISK ASSESSMENT			
Name:	Position:	Faculty:	Department:
Proposed start date for this work:-		Proposed finish date (if known):-	
Date risk assessment undertaken:-			

4. LOCATION OF ACTIVITIES *Give details of where different activities will take place e.g. include manipulation, growth, storage, disposal, centrifugation etc.*		
Activity	Room	Containment Level

BMBL refers to the 5th Edition of *Biosafety in Microbiological and Biomedical Laboratories*. The full version or individual parts of the text in pdf downloadable format can be found at:- http://www.cdc.gov/OD/ohs/biosfty/bmbl5/bmbl5toc.htm. The whole text is also available on the university safety office website under the safety manual heading and the subheading of biosafety. The University Biosafety committee will accept the classification of microorganisms detailed in this publication.

PART 2 RISK ASSESSMENT

1. PROJECT TITLE

2. OVERVIEW OF PROJECT *This information should provide both the scientific goals of the project and a simple explanation of the work so that the average member of the public can understand. If presenting the scientific goals poses problems in relation to intellectual property rights or commercial sensitivity please discuss further with the BSO.*

3. HAZARDS ASSOCIATED WITH THE WORK								
If a commercial system is being used please provide a web link to the manual that includes safety data and details of the system. If obtained from colleagues please provide a reference with details of the vector system.								
3.1 Is the system/s to be used based on:- i. Moloney Mouse Leukaemia virus (MMLV)							Yes ☐	No ☐
ii. Murine Stem Cell Virus (MSC)							Yes ☐	No ☐
iii. Lentivirus	a) HIV	Yes ☐	No ☐	b) EIAV	Yes ☐	No ☐	c) Other Lentivirus or Lentivial vector expression system- please specify	
iv. Retrovirus other than MMLV or MSC, please specify:-								
3.2 Please give a general overview of system being used and the planned work (e.g. method of virus production, if animal work is to be carried out, whether the system is 1st, 2nd or 3rd generation etc). Please note that there is no need to repeat what is in section 2.								

3.3 What is the host range of the retrovirus that will be produced?								
Ecotropic	Yes ☐	No ☐	Xenotropic	Yes ☐	No ☐	Amphotropic	Yes ☐	No ☐

3.4 What envelope proteins are going to be used ? Will VSV-G pseudotyping be used to expand the host cell range of any viruses or viral vector expression systems used ?

3.5 Is there any potential for the generation of Replication Competent Retroviruses? i.e. are there common sequences in plasmids or cells lines that will allow homologous recombination to occur?

3.6 Will a continuous recombinant retrovirus vector producer cell line be generated?	Yes ☐	No ☐
If yes will replication competent retroviruses (RCR) be tested for?	Yes ☐	No ☐

If yes please details of how this will be done and if not please explain why not.

3.7 Please indicate the recombinant genes to be expressed, the activity of the gene and the promoter used to control expression. Include siRNA molecules under gene to be expressed and indicate what the result of modulating the expression of the target gene might be.		
Promoter Used	Gene to be expressed	Activity of gene/ consequence of expression

3.8 Please indicate what potential there may be for insertional mutagenesis? Also include in the information whether a SIN LTR is being used.

3.9 Is there potential in the proposed work for mobilization of the integrated gene/ expression cassette by co-infecting or endogenous retroviruses? – If yes please explain.

Preliminary Classification (please tick):-	BSL 1 ☐	BSL2 ☐	BSL3 ☐

3.10 Identify potential routes of infection in the laboratory:-					
Percutaneous Yes ☐ No ☐	Inhalation Yes ☐ No ☐	Ingestion Yes ☐ No ☐	Splash in eye or mouth Yes ☐ No ☐	Animal bite/scratch Yes ☐ No ☐	Needlestick Yes ☐ No ☐

4. SUMMARY OF THE WORK

i) Description of the procedures: (Please describe the nature of the work to be carried out. This might include growth, purification, storage and administration to animals. Identify any procedures that require additional controls e.g. the use of sharps, production of aerosols etc)

ii) Substances used: (Section 3 has details of specific organisms, however where appropriate give details of materials used such as clinical and environmental samples)

iii) Quantities and frequency used: (This is vital if potential exposure and hence risk is to be assessed properly. Please indicate the scale of the work in terms of the maximum culture volumes and the likely number of times the procedures will be carried out.)

5. CONTROLLING THE RISKS: (Hierarchy of Controls)

5.1 Substitution: Is substitution with a safer alternative practical? For example can a SIN LTR be used or a transient packaging system be used in the place of a continuous cell line. Please explain your conclusions.

5.2 Engineering Controls: (Specify if they are required e.g. for airborne microbiological hazards the use of a biological safety cabinet may be necessary, if so, identify the type required - Class 1, Class 2 or Class 3)

5.3 Administrative controls:

i. Is the work adequately isolated/ segregated?

a. Is/ are the room(s) shared with other workers not involved directly in this activity? If so give details. Also indicate arrangements for maintenance staff and cleaning arrangements.

b. Is access to the laboratory restricted? Please provide details.

ii. Assignment of Containment level: With particular reference to section 3.10 please specify the containment level required and any other control measures necessary. Local codes of practice may be referenced. Other controls may include a stringent sharps policy, ensuring sealed rotors are used, limiting the quantity of agent used, the prohibition of lone working or specifying the level of supervision required,

iii. Waste disposal procedures: Add lines as required. Liquid waste might include cultures and culture medium, while solid waste includes items such as culture flasks. Clinical Waste might include human samples, blood, carcasses, sharps etc

	Detail of type of waste	Treatment before disposal	How disposed
Liquid Waste			
Solid waste			
Clinical Waste			

iv. Emergency Procedures: These should be detailed in the local code of practice, a brief summary is appropriate here.

v. Transport: Transport within the laboratory and between laboratories (including between campuses) should be documented in the local code of practice, a brief summary is appropriate here. How will these agents be transported within the laboratory to avoid splashes and spills e.g. between the incubator and safety cabinet?

5.4 Personal Protective Equipment (PPE): Please indicate what is required. Laboratory Coats must always be worn but the need for gloves, aprons, eye and respiratory protection etc will vary.			
Lab Coat	Gloves	Eye or face (specify if yes)	Other (specify)
Yes ☐	Yes ☐ No ☐	Yes ☐ No ☐	

6. ENSURING CONTROL MEASURES ARE USED AND MAINTAINED

Please indicate what, if any, checks on control measures are required e.g. annual maintenance of biological safety cabinets (also note the frequency of inspection needed).

7. OCCUPATIONAL HEALTH ISSUES

Please indicate if environmental or personal monitoring is required. (This is required only in exceptional circumstances where biological agents are concerned. If in doubt discuss the issue with the University BSO)

Please indicate if Health Surveillance is required. (Advice can be obtained from the University BSO and is only appropriate in a few circumstances).

Please indicate whether vaccination is required. All those handling clinical specimens are expected to receive hepatitis B virus vaccination with post immunisation monitoring of antibody levels to ensure effective protection has been achieved.

8. INSTRUCTION INFORMATION AND TRAINING

Please indicate if there any specific training requirements:

9. SIGNATURES	
The name and signature of the person making the assessment is required. Heads of department may also wish to sign but this is not necessary, however if the assessment is made by a student (undergraduate or postgraduate) or research assistant then their supervisor or PI should also sign.	
Name of Assessor: Signature:	Date:
Name of Reviewer: Signature:	Date:
Head of Department: Signature:	Date: