BIOSAFETY SCHEDULE A: NON-EXEMPT RECOMBINANT DNA

1. **(a) Are you using recombinant viral vectors or other non-exempt vector backbones?** ☐Yes ☐No
   - *If "no", please proceed to Question 2 of this Schedule.*
   - *If "yes", please complete charts and description(s) below to describe which viral sequences have been deleted from the wild-type vector (e.g. rendering a replication competent vector replication incompetent), and the packaging systems in which these vectors will be used for the production of viral particles.*

Vector Technical Name	**Viral (or non-exempt vector) Backbone Source (e.g. MLV, MSCV, HIV, Vaccinia, Adenoviral, AAV, Plasmids from Risk Group 2 organisms)**	**Regions of viral genome deleted or altered (if any) to produce viral vector** (*i.e.* what is the basis of vector attenuation or replication incompetence, if any)	**% of viral genome included in constructs** (or provide map or reference for vector construction)	**Is the vector designed to be replication competent?**
				☐Yes ☐No
				☐Yes ☐No
				☐Yes ☐No
				☐Yes ☐No
				☐Yes ☐No

Name of Packaging Cell line(s) or Helper plasmids used in co-transfect ion to produce viral particles	**Source(s) of cells (i.e. species)**	**Tropism** (i.e. what species of cells can the virus infect?)	**Source of envelope glycoproteins** (if retro- or lentivirus)

(b) Please describe the insert(s) (if any) to be used in the above vectors.
Include sufficient information for a Risk Assessment by the IBC, which may include answers to the following questions, as appropriate:

i. *What is the gene source (species and/or strain)*
ii. *What is the nature of the insert(s) (e.g. which protein(s), siRNA are encoded by the insert)*
iii. *What is the anticipated effect upon expression of the insert(s) (if known)?*
iv. *How will these constructs be utilized (what are the target cells and/or animals for these constructs)?*
v. *Have these agents been previously passaged through animals or other cells or cell lines?*
vi. *At what point in your experiments will your agents be inactivated or lysed?*

(c) **Will you be assaying for the production of wild-type/helper/replication competent viral particles?** ☐Yes ☐No

If "yes", please describe methods and stage in your experiment at which these assays will be performed.

2. **Are you using any non-exempt recombinant DNA** **inserts** **(*e.g. toxins with LD_{50}<100 µg/kg body weight, antibiotic resistance cassettes or regions of genomes from Risk Group 2, 3 or 4 or restricted organisms)?*** ☐Yes ☐No
   - *If "no", please proceed to Question 3 of this Schedule.*
   - *If "yes", please describe these inserts and their associated vectors. Include sufficient pertinent information for a Risk Assessment by the IBC, which may include answers to the following questions, as appropriate:*
     - *a. What is the gene source (species and/or strain) of the insert?*
     - *b. Into which vectors are these non-exempt inserts being cloned?*
     - *c. What is the nature of the insert(s) (e.g. which protein(s), siRNA are encoded by the insert)*
     - *d. What is the anticipated effect upon expression of the insert(s)?*
     - *e. How will these constructs be utilized (what are the target cells and/or animals for these constructs)?*
     - *f. At what point in your experiments will your agents be inactivated or lysed?*

3. **Are you expressing any recombinant DNA in microbial pathogens (*e.g.* in risk group 2, 3, or 4 bacteria, yeast, fungi or parasites or microbes requiring ≥BSL2 containment)?** ☐Yes ☐No
   - *If "no", please proceed to Question 4 of this Schedule.*
   - *If "yes", please describe the pertinent information to enable the risk assessment process, including:*
     a. *The nature of the recombinant DNA construct (vector and insert)*
     b. *Which microbial host cells is this recombinant DNA will be introduced.*
     c. *What are the anticipated effects of introduction of the recombinant DNA into the host (if known)*
     d. *At what point in your experiments will your agents be inactivated or lysed?*

4. **List approximate maximum volume(s) of cultures** of these agent(s) generated at any one time. Note: if any cultures are ≥10 liters, please include Schedule C in application.

5. **Describe any procedures that will be performed with this material which may be associated with an increased potential risk of exposure of personnel** (*increased risk of exposure may be associated with generation of splashes, sprays or aerosols from centrifugation, sonication, homogenization, vortexing, FACS, use of sharps (needles, glass or syringes), cage cleaning of infected animals, animal surgeries, etc. Management of these risks should be addressed in the PI's laboratory-specific SOPs)*

6. **Will you be introducing any recombinant DNA or genetic engineered material into animals**? ☐Yes ☐No
   If "yes", you will also need to apply for IACUC approval ***in addition to IBC approval*** *before beginning your research. You will also need to include Biosafety Schedule E with this application.*

7. **Will you be introducing these biological agents into humans?** ☐**Yes** ☐**No**
   If "yes", ***in addition to IBC approval****, your research will require IRB approval and likely review by the Recombinant DNA Advisory Committee of NIH before beginning your research. You will also need to include Biosafety Schedule B with this application.*

8. **Will these experiments result in acquisition of new characteristics of any infectious agents**, such as altered virulence or infectivity, or changes in resistance/susceptibility to drug therapy or changes in host range? ☐Yes ☐No
   If "yes", please describe: