StFX Biosafety Committee

RECOMBINANT DNA **BSF-6**

Principal Investigator: _____

Project Title: _____

Dual Use Research is biological research with legitimate scientific purpose, the results of which may be misused to pose a biologic threat to public health and/or national security.

1. This project involves Dual Use Research (*check all that apply*):

   ☐ renders a useful vaccine ineffective

   ☐ adds antibiotic resistance affecting response to a clinically useful drug

   ☐ enhances pathogen virulence

   ☐ enables production of a novel toxin

   ☐ increases pathogen transmissibility

   ☐ alters a pathogen's host range

   ☐ enhances a pathogens ability to evade diagnostic or detection methods

   ☐ enables weaponization (e.g., environmental stabilization of pathogens)

   ☐ none of the above apply

2. Host/Vector/Nucleic acid information. *(If host is pathogenic, complete BSF-2)*
   Check all that apply:

   Host

   ☐ Yes ☐ No is a cell or organism other than E-coli K-12, *Saccharomyces cerevisiae, Bacillus subtilis, or Bacillus licheniformis*.

   Vector to be used to introduce foreign DNA or RNA into the host:

   ☐ Yes ☐ No is from a RG 3 agent.

   ☐ Yes ☐ No Insertion of foreign DNA or RNA into a vector or organism to clone or express it

DNA or RNA to be cloned or expressed:

☐Yes ☐No DNA or RNA is from a Risk Group (RG) 2 or RG 3 organism

☐Yes ☐No DNA or RNA represents more than two-thirds of the genome of a RG 1 or RG 2 organism

☐Yes ☐No DNA or RNA encodes a known oncogene

☐Yes ☐No DNA or RNA encodes toxin molecules with a LD50 of <100 nanogram/kg of body weight

☐Yes ☐No is a RG 1 or RG 2 virus that infects eukaryotic cells and contains more than two-thirds of the viral genome.

3. Human Gene Transfer

☐Yes ☐No the project will involve the deliberate transfer of recombinant DNA or RNA into one or more human subjects. (*If yes, attach research ethics approval documentation.)*

4. Recombinant DNA Materials:

RECOMBINANT DNA MATERIALS			
Host Organism/Strain Number		**Genotype**	**Risk Group *(See Appendix B, NIH Guidelines)***
H1			
H2			
H3			
H4			
Viral Vectors (*If viral, indicate % of viral genome remaining*) Examples: poxvirus, adenovirus, retrovirus, etc.			
	Name, Class, % genome	**Replication competent**	**If replication deficient, explain mechanism**
VV1			
VV2			
VV3			
VV4			

Other Vectors Class Examples: nonconjugative, conjugative, mobilizable, lamboid, F bacteriophage, etc.			
	Name and Class	**Bacterial Host Range (Narrow range, e.g., *E. coli* and close relatives)**	**Extended Host Range (Broad range, e.g., *E. coli*, yeast, mammalian, etc)**
OV1			
OV2			
OV3			
OV4			
Vectors will be: ☐ constructed in the lab ☐ purchased from a vendor ☐ obtained elsewhere (specify):			

Inserted DNA Sources: specify nature/gene (e.g., genomic, cDNA, synthetic, coding or non-coding sequences) and biological activity (e.g., structural protein, enzymatic protein, oncogene, toxin, cell growth, etc.)	
D1	
D2	
D3	
D4	
Helper Virus required:	☐ Yes ☐ No
Foreign Gene Expression (*specify protein, toxin, antigen, etc*):	

5. This project involves a combination of host(s) and vector(s) that could lead to conjugal transfer of recombinant molecules: ☐ Yes ☐ No (If yes, explain):

6. This project involves greater than 10 L of cell culture: ☐ Yes ☐ No

7. Target recipient of vector-recombinant DNA combination (*specify species or cell lines used*):

☐ Prokaryote: _____

_____

☐ Tissue culture: _____

_____

☐ Animals: _____

☐ Plant cells: _____

☐ Plants: _____

☐ Gene therapy
(specify host): _____

☐ DNA vaccine
(specify target recipient): _____

8. Physical Containment Level (see Appendix G, NIH Guidelines): _____

9. This project involves the use of Biological Containment: ☐ Yes ☐ No

Explain:

Biological Containment Level (*see Appendix 1, NIH Guidelines*): _____

10. Will the recombinant DNA be deliberately released into the environment?

☐ Yes ☐ No (*If yes, contact the Chair, StFX Biosafety Committee*)

11. Disposal/inactivation method:

_____

_____

_____

12. References. Note any references that may support this application.

_____

_____

_____

13. Certification by the Principal Investigator:

I have reviewed the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (2016) and accept the responsibilities described therein for Principal Investigators (Section IV-B-7).

Name: _____

Signature: _____

Date: _____