Calvin College Biosafety Application

SECTION 1: GENERAL INFORMATION

Applicant Name: _____ Campus Address: _____

Email Address: _____ Campus Phone #: _____

Project Title: _____

APPLICATION TYPE: Research ☐ Teaching☐ Course #(s) _____

PROTOCOL TYPE: New☐ Renewal☐ Modification☐ Approval No.: _____

Please select all of the following that apply to the biological materials in this application

☐	RG 1, or unknown, or potentially infectious agents (including cell lines)	SECTION 1
☐	Infectious agents and/or biological agents listed by National Institutes of Health in Risk Group 2 & 3 (see Appendix B in the NIH Guidelines)	SECTION 1 & 2
☐	Human and non-human primate cells, tissue and/or blood	SECTION 1, 2, & 3
☐	Recombinant DNA	SECTION 1, 2, & 4
☐	Select agents and biological toxins identified by the Centers for Disease Control	PROHIBITED

Provide the name of the agents(s), NIH Risk Group, and containment level (use separate sheet if needed):

Name of Agent/Material	Risk Group				Containment Level		
	1	2	3	Not Defined	BSL-1	BSL-2	BSL-2+

Please answer the following questions (explain all "yes" answers in Section 2):

Is this agent on the USDA list of High Consequence Plant or Livestock Pathogens and Toxins?	☐Yes ☐No
Will the agent be genetically modified (mutagenesis, insertion of genes etc.) in this protocol?	☐Yes ☐No
If "yes", is it possible that modifications will increase virulence or expand host range of the agent?	☐Yes ☐No
Will you be administering this agent (in modified or unmodified form) to animals?	☐Yes ☐No
Will you be administering this agent (in modified or unmodified form) to plants?	☐Yes ☐No
Will you be using vertebrate blood or tissue infected with this agent?	☐Yes ☐No
Will aerosols be generated with the agent?	☐Yes ☐No
Will you be shipping infectious agents offsite?	☐Yes ☐No
Are additional vaccines required for use of this agent/material?	☐Yes ☐No
How will this material be acquired & where is it from? (existing stocks, drawn on site, purchased, etc. Include vendor name)	
Where will agents be used (room & bench, BSC/hood)?	Where will the agents be stored? Provide room # and storage device (-80, fridge, liquid N)
Provide the names and/or job titles of additional personnel working on this project (including students):	

Certification: I certify that to the best of my knowledge, the information provided in this application is complete and correct. I am familiar with, and agree to abide by the provisions and guidelines established by the NIH, CDC, and GVSU IBC, that pertain to the research project described in this application.

Signature: _____ Approval: _____

Principal Investigator/ Laboratory Coordinator

Signature of IBC Chair

Date: _____

Approved Protocol Number _____

Date: _____

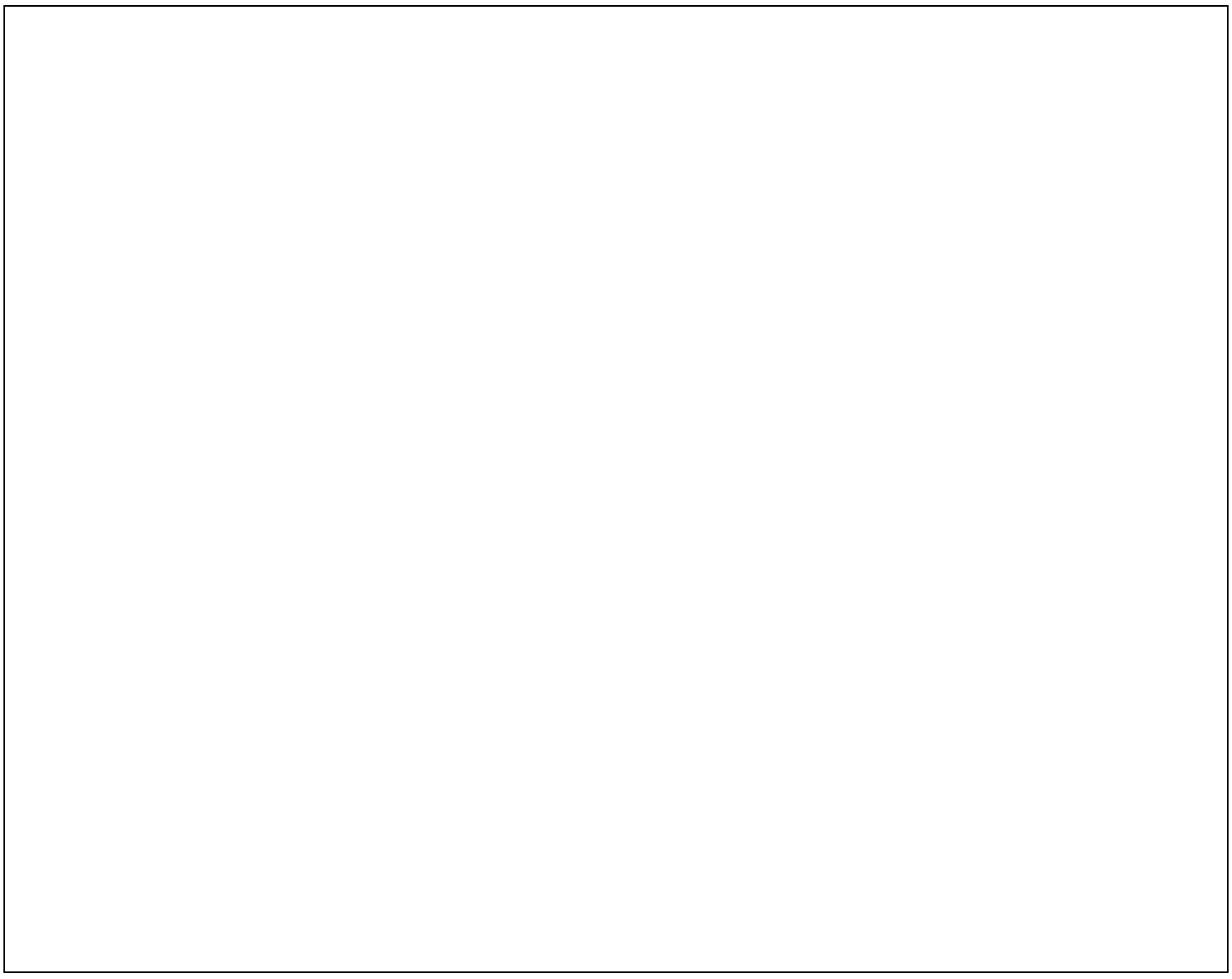
Valid until: _____

SECTION 2: EXPERIENCE and PROJECT DESCRIPTION

Please describe your experience or background as it relates to this protocol. A CV is not required, but you may include yours.

Either in the space below or on a separate sheet, describe how the infectious agents, recombinant DNA or vertebrate tissue will be used. The project summary should be written using non-technical terms and presented in a manner that can be fully understood and evaluated by individuals outside of the researcher's area of expertise. The summary should include:

☐	Description of proposed use and objectives	☐	Personal protection requirements
☐	Experimental design and procedures	☐	Inactivation, cleanup, and disposal method
☐	Health and safety hazards associated with exposure	☐	Exposure and spill response procedures
☐	Description of procedures to minimize exposure	☐	Description of PI experience with biohazardous materials and employee training
☐	Storage and/or containment procedures		



SECTION 3 - APPLICATION FOR USE OF VERTEBRATE BLOOD AND TISSUE INCLUDING HUMAN OR OTHER PRIMATE CELL LINES

1, DESCRIPTION OF VERTEBRATE TISSUE or CELL LINES

Name the tissue or cell line to be used in the project and the species from which it is derived.
Will the tissue or cells contain a known infectious agent? ☐Yes ☐No
Is IRB approval required for this protocol? ☐Yes ☐No
If yes, what is the protocol # or status of that application?
Is IACUC approval required for this protocol? ☐Yes ☐No
If yes, what is the protocol # or status of that application?
How will the tissue or cells be disposed?
Will you be shipping or transporting this tissue to or from the college? ☐Yes ☐No
If yes, please describe the procedure.
Have individuals involved with the protocol completed the necessary training (ex: BBP and/or biosafety)? ☐Yes ☐No
If not, when will it be completed?

What safety procedures should the personnel take to protect themselves from this material above universal precautions be taken and have personnel received Blood borne Pathogen Training?

SECTION 4 - APPLICATION FOR USE OF RECOMBINANT DNA AND/OR TRANSGENIC ORGANISMS

1. DESCRIPTION OF DNA INSERTS.

Describe the nature of the DNA insert molecules that will be used in this project. Provide the gene name(s) and acronym(s) if appropriate, the biological source/origin (mouse, virus, bacteria, etc), and all pertinent biological activities of the encoded protein(s) (normal biological function, oncogenic potential, toxicity, etc.).

Is the expressed protein a toxin known to affects humans and/or animals?	☐Yes ☐No
If yes, is the toxin on the CDC Select Agent List?	☐Yes ☐No

2. DESCRIPTION OF VECTOR.

Will recombinant DNA be inserted into a virus, replicon, bacterial plasmid, BAC or other vector?	☐Yes ☐No
What containment level will be used for experiments involving this vector?	☐BSL-1 ☐BSL-2 ☐BSL-2+ ☐BSL-3
If the vector is a virus, is the vector replication-competent?	☒Yes ☐No
Identify vector & packaging system in the chart below:	

	Construct 1	Construct 2	Construct 3	Construct 4	Construct 5	Example
Name and Provider of Gene						Example: green fluorescent protein from Clontech
Gene Function						Example: marker
Vector Name						Example: pKH-WSU24
Vector Type / Species and Strain						Example: Viral / Adenovirus serotype 5
Expression control elements (promoters, enhancers, etc)						Example: CMV promoter
Conc/titer of rDNA (i.p./ml)						Example: 1 X 10^8 to 1 X10^{12} infectious particles/ml
Host and Strain, if applicable						Example: E. coli, Sure™, Mouse heart cells, in vivo
Largest Production Volume of Host						Example: 1 liter

Host Range (including any genetic alterations to host range)						Example: amphotropic, broad mammalian host range
Is recombinant made in your lab? If not, where?						Example: Vanderbilt Univ. Gene Therapy Center
If vector is a genome, what % has been deleted or substituted?						Example: 10%

3. DESCRIPTION OF HOST.

A. Cell Culture Host

Will recombinant DNA molecules be inserted into a bacterial or eukaryotic host cell? (e.g. E. coli, yeast, eukaryotic cell line)? ☐Yes ☐No
If yes, identify the host organism or cell type/line.
What containment level will be used for experiments involving this host? ☐BSL-1 ☐BSL-2 ☐BSL-2+ ☐BSL-3
Will cultures be grown in amounts of 10 liters or more? ☐Yes ☐No

B. Transgenic Animals

Will recombinant DNA be introduced into animals (i.e. as recombinant virus or expression plasmid) or used to produce transgenic animals? ☐Yes ☐No
If yes, explain.
If yes, indicate the status of your IACUC protocol and IACUC Appendix E (for production of transgenic animals).

C. Transgenic Plants

Will recombinant DNA be used to produce transgenic plants? ☐Yes ☐No
If yes, explain.
If yes, indicate status of USDA Permit
Or, provide USDA Permit #

4. SPECIAL SAFETY CONSIDERATIONS.

Are there any special safety considerations associated with the use of any of the recombinant DNA molecules, gene products, vectors, or hosts used in this research project?	☐Yes ☐No
If yes, explain.	
Will you be shipping or transporting these recombinant DNA molecules to or from the university?	☐Yes ☐No
If yes, please describe the procedure.	

5. CATEGORIZATION of EXPERIMENTS ACCORDING TO NIH GUIDELINES for RESEARCH INVOLVING RECOMBINANT DNA MOLECULES.

Please select the specific subsection from Section III of the NIH Guidelines (e.g. III-D-3-a) under which you believe this research is covered.

Section III-D. Experiments that Require Institutional Biosafety Committee Approval Before Initiation

☐	1	**Experiments Using Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents as Host-Vector Systems** (Experiments involving the introduction of recombinant or synthetic nucleic acid molecules into Risk Group 2 agents.)
☐	2	**Experiments in Which DNA From Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents is Cloned into Nonpathogenic Prokaryotic or Lower Eukaryotic Host-Vector Systems** (Experiments in which DNA is transferred into nonpathogenic prokaryotes or lower eukaryotes.)
☐	3	**Experiments Involving the Use of Infectious DNA or RNA Viruses or Defective DNA or RNA Viruses in the Presence of Helper Virus in Tissue Culture Systems** (Experiments involving the use of infectious or defective viruses (see Appendix B-II, Risk Group 2 Agents) in the presence of helper virus.)
☐	4	**Experiments Involving Whole Animals** (Experiments involving whole animals in which the animal's genome has been altered by stable introduction of recombinant or synthetic nucleic acid molecules, or nucleic acids derived therefrom, into the germ-line (transgenic animals) and experiments involving viable recombinant or synthetic nucleic acid molecule-modified microorganisms tested on whole animals.)
☐	5	**Experiments Involving Whole Plants** (Experiments to genetically engineer plants by recombinant or synthetic nucleic acid molecule methods, to use such plants for other experimental purposes (e.g., response to stress), to propagate such plants, or to use plants together with microorganisms or insects containing recombinant or synthetic nucleic acid molecules.)
☐	6	**Experiments Involving More than 10 Liters of Culture**
☐	7	**Experiments Involving Influenza Viruses**

Section III-E. Experiments that Require Institutional Biosafety Committee Notice Simultaneous with Initiation (Experiments not included in Sections III-A, III-B, III-C, III-D, III-F, and their subsections are considered in Section III-E.)

Please explain:

Section III-F. Exempt Experiments

Please explain:

Biosafety Officer Section Only

I have reviewed this application and

BSO approves; no further action required by IBC BSO requires full committee review

BSO signature: _____ Date: _____