**Instructions for Completing the Biosafety Application**

Calvin University

Institutional Biosafety Committee

Please use the attached application for requesting a review and approval of activities involving biohazardous agents by Calvin’s Institutional Biosafety Committee (IBC). This application should be used for all activities including research, teaching, and testing. The IBC requests the information in accordance with its charge. This information is required by the Occupational Safety and Health Administration's Occupational Exposure to Hazardous Chemicals in Laboratories Standard, its Blood-Borne Pathogen Standard and/or the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (rDNA or SNA).

Use the Biosafety application form for:

New Applications

Renewal of previously approved protocols. Renewals fall into two categories:

1. Renewal without modification. Complete page 1 of the application including the Approval Number from your original application
2. Renewal with modifications. Modifications may include personnel or room changes to adding/changing infectious agents, viral vectors, transgenes, etc.

For Renewal with modifications complete page 1 of the application including the Approval Number from your original application and then complete the Amendment Form found at the end of the Biosafety Application.

Please allow the Biosafety Officer and/or IBC at least two weeks for review of application.

Submit completed application(s) to:

Lori Keen

Biological Safety Officer

Calvin University

Biology Department

1726 Knollcrest Circle SE

Grand Rapids, MI 49546

(616) 526.6080

BSO@calvin.edu

Contact the BSO if you have questions or need assistance when completing the application.

**Calvin University Biosafety Application**

# APPLICANT INFORMATION

|  |  |
| --- | --- |
| Applicant Name: Address: Email Address: Phone: Project Title:  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| APPLICATION TYPE: | Research [ ]  | Teaching [ ]  | Course #(s)  |
| PROTOCOL TYPE: | New [ ]  | Renewal [ ] w/out modifications | Renewal [ ] w/ modifications | Approval No.: (if renewal or modification) |

***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, the Calvin University IBC, and WMRL (if applicable) that pertain to the research project described in this application.

Signature: DATE

Principal Investigator

 **Biosafety Officer Section Only**

 I have reviewed this application and

 [ ]  BSO approves; no further action required by IBC

 [ ]  BSO approves for designated member review (special expertise may be required)

 [ ]  BSO requires full committee review

 Name:

 Date:

 (Signature of Biosafety Officer)

FINAL APPROVAL

Approved by BSO/IBC Chair Signature:

Approved Protocol Number: DATE:

VALID UNTIL:

# SECTION 1: GENERAL PROJECT INFORMATION

## Please select any of the following that apply to the biological materials in this application and complete the indicated sections of the application

|  |  |  |
| --- | --- | --- |
|  | **BIOLOGICAL MATERIALS TO BE USED** | **SECTIONS TO COMPLETE** |
| [ ]  | RG 1, or unknown, or potentially infectious agents (including cell lines) | SECTION 1 |
| [ ]  | Infectious agents and/or biological agents [listed](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.html#_APPENDIX_B._CLASSIFICATION) by National Institutes of Health in Risk Group 2 & 3 (see [Appendix B](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.html#_APPENDIX_B._CLASSIFICATION) 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):**

|  |  |
| --- | --- |
| 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 |
| Is this agent on the USDA list of High Consequence Plant or Livestock Pathogens and Toxins? | [ ]  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 #, open bench, BSC)? | Where will the agents be stored? Provide room # and storage device (-80, refrigerator, liquid N2) |
|  |  |
| Provide the names and/or job titles of additional personnel working on this project (including students): |
| EXPAND FOR MORE NAMES |

# 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 (brief) | [ ]  | Personal protection requirements |
| [ ]  | Experimental procedures | [ ]  | Inactivation, cleanup, and disposal method |
| [ ]  | Assessment of exposure risks to personnel | [ ]  | 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 university? | [ ]  Yes [ ]  No |
|  |
| If yes, please describe the procedure. |
|  |
| Have individuals involved with the protocol completed the necessary training (ex: BBP and/or biosafety)? Last training date: | [ ]  Yes [ ]  No |
| If not, when will it be completed? |
|  |

In addition to Universal Precautions, what specific safety procedures will personnel take to protect themselves from exposure to this material? Include PPE, engineering controls utilized, safety devices, etc.

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

## 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](https://www.selectagents.gov/selectagentsandtoxinslist.html)? | [ ]  Yes [ ]  No |

## 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+  |
| 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** |
| **N****ame and Provider of Gene** | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Example: green fluorescent protein from Clontech |
| **Gene Function** | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Example: marker |
| **Vector Name** | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Example:pKH-WSU24 |
| Vector Type / Species and Strain | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Example: Viral / Adenovirus serotype 5 |
| Expression control elements (promoters, enhancers, etc) | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Example: CMV promoter |
| Conc/titer of rDNA (i.p./ml) | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Example: 1 X 108  to 1 X1012 infectious particles/ml |
| **Host and Strain, if applicable** | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Example: E. coli, SureTM, Mouse heart cells, in vivo |
| **Largest Production Volume of Host** | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Example:1 liter |
| **Host Range (including any genetic alterations to host range)** | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Example: amphotropic, broad mammalian host range |
| **Is recombinant made in your lab? If not, where?** | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Example:Vanderbilt Univ. Gene Therapy Center |
| **If vector is a genome, what % has been deleted or substituted?** | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Example: 10% |

1. **DESCRIPTION OF HOST**
	1. 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+  |
|  |
| Will cultures be grown in amounts of 10 liters or more? |  | [ ]  Yes [ ]  No |

* 1. 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). |
|  |

* 1. 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 # |
|  |

## 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 Calvin University or WMRL? | [x]  Yes [x]  No |
| If yes, please describe the procedure. |
|  |

1. **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](http://osp.od.nih.gov/sites/default/files/NIH_Guidelines_0.pdf) (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 nucleicacids 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 tostress), 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:

**Calvin College IBC**

**Amendment Form**

|  |  |
| --- | --- |
| Principal Investigator: | Click here to enter text. |
| Email: | Click here to enter text. |
| IBC protocol #: | Click here to enter text. |
| Project title: | Click here to enter text. |
| Originally approved on: | Click here to enter text. |
| Protocol amendment #: | Click here to enter text. |
| Biosafety level: | Click here to enter text. |
| Office phone: | Click here to enter text. |
| Lab location: | Click here to enter text. |

Perform a risk assessment per Section II-A-3 of the [NIH Guidelines](http://oba.od.nih.gov/oba/rac/Guidelines/NIH_Guidelines_new.pdf) in order to determine the appropriate level of review by the IBC.

MINOR AMENDMENT\*:

[ ]  Adding/changing/removing materials covered by the Bloodborne Pathogens Standard, or cell culture line of the same Risk Group

[ ]  Adding/removing co-investigators or technicians (please list names and whether they are being added or removed on page 2)

[ ]  Adding/changing/removing BSL-1 or BSL-2 laboratory room numbers:

 Current room number(s):

 Proposed room number(s):

[ ]  Adding/changing/removing exempt transgenic animals or research

 IACUC study #:

[ ]  Other

\*Submit amendment form and any supporting documents. The amendment will be considered by an IBC member for expedited review.

MAJOR AMENDMENT\*\*:

[ ]  Adding/changing genetically modified cell or tissue culture line

[ ]  Adding/changing transgene

[ ]  Adding/changing infectious agents, toxins, or viral vectors

[ ]  Adding/changing non-exempt transgenic animal species or research

 IACUC Study #

[ ]  Adding/changing non-exempt invertebrate animal species or research

[ ]  Adding/changing transgenic plants or plant species used in research with genetically modified organisms

[ ]  Upgrade in containment level:

 Current Biosafety Level:

 Proposed Biosafety Level:

[ ]  Other

\*\*Submit amendment form, revised Biosafety Application, and any supporting documents. The amendment will be considered in a convened meeting of the Institutional Biosafety Committee.

A major amendment requires IBC approval PRIOR to initiation of work. See page 2 of this document.

Describe the proposed changes and rationale for the changes:

|  |  |  |
| --- | --- | --- |
| **NAME** | **Biosafety Training Date Completed (required annually)** | **Project Responsibilities** |
| **PI:** Click here to enter text. | Click here to enter text. | Click here to enter text. |
| Click here to enter text. | Click here to enter text. | Click here to enter text. |
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| Click here to enter text. | Click here to enter text. | Click here to enter text. |
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**Note to investigators**: Study amendments may not be instituted until approval from Calvin’s IBC has been given. Retain a copy of this form for your records.

Investigator: Date:

*Please return this form and any associated documentation to the* *Biosafety Officer**.*