INSTITUTIONAL REVIEW BOARD

APPLICATION FOR REVIEW OF PROJECTS INVOLVING BIOLOGICAL & BIOMEDICAL RESEARCH (INCLUDING RECOMBINANT DEOXYRIBONUCLEIC ACID)

FOR INTERNAL USE ONLY **TU IRB APPLICATION NUMBER:_____**

The Thomas University Institutional Review Board (IRB) requires that students, faculty and researchers submitting an IRB application to conduct biological/biomedical research complete the appropriate online Collaborative Institutional Training Initiative (CITI) certification courses available at https://www.citiprogram.org/index.cfm?pageID=14&languagePreference=English&region=1
Please be sure to select Thomas University as the affiliate institution on the CITI website to see the list of required courses per research area.

Please note: Handwritten applications will *not be* accepted.

Application Type: ___NEW ___ RESUBMISSION Date Application Submitted to IRB: ____/___/_____
___FOR ACADEMIC TEACHING PURPOSES ONLY *(FACULTY ONLY)*

Title of Project: _____

Name of Principal Investigator: _____
Department:
Address:
Phone:
Fax:
Email:

Co-Investigator(s): List the full name(s), title(s) and department(s) of all Co-Investigator(s) – Cite ***both your and their experience*** with this kind of research – include your name within the co-investigator(s) group to distinguish your experience among the group as the principal investigator. (If no one but you will be collecting data, state that fact.)

Faculty Sponsor: _____
Department:
Phone:
Email:

IRB Submission: Have you submitted this study to any other IRB? **No____Yes____**

A. What IRB(s)? List name of Institution(s)_____

B. What category of review was the project submitted as?_____

C. Status of review (i.e. approved, not approved, pending). If the project was approved, please attach a copy of the approval letter.

Joint Institutional Research: Describe how permission has been obtained from cooperating institution(s) – i.e., school, hospital, prison, or other relevant organization. *(Attach letters of permission and approval.)*

Does this cooperative research require additional IRB permission from another institution?
_____YES _____NO

Estimated date to begin data collection: (pending IRB approval)_____

Duration of project: (Please remember you may not begin data collection without IRB approval)
Start Date:_____ ***Ending Date:***_____

Sponsorship:

____Project **does not require funding** from an outside source or a commercial sponsor

____Project **requires funding** from an outside source or a commercial sponsor

a. Commercial sponsor clinical contact name_____
b. Commercial sponsor clinical contact telephone number_____
c. Funding source:_____
____Funding obtained
____Funding application pending
____Funding application to be submitted, deadline_____

Please explain the *scientific merit* of the study in the space provided:

General Outline of Proposed Study

A. Describe the research design – include objectives, procedures *(include number of times observations, examinations, tests, etc. will be conducted)* and expected results. **Specifically include the following:**

1. Host strain(s) used, (include genus, species, and parent strains);

2. Source of DNA/RNA sequences (include genus, species, gene name and abbreviations, function of the gene);
3. Recombinant plasmid(s)/vectors used;
4. If there will be any attempts to obtain expression of foreign gene(s) - identify the gene(s) and gene(s) functions; and
5. Explain containment and safety precautions to be utilized in the proposed work and indicate where work will be conducted (i.e., Biological Safety Cabinet, other facilities); how material will be disposed of and what precautions will be taken by those handling materials. If *relevant, list specific type of biological safety cabinets that will be used.*

B. Aims and objectives- ***In lay or non-technical terms*** (language understood by a non-scientific member of the community), provide a 1-2 paragraph overview of the aims and objectives of this study. Avoid scientific jargon and define all abbreviations. Include a justification for how this study promotes animal or human health or advances scientific knowledge.

C. If you know that this research is ***exempt*** from review according to the *NIH Guidelines for Recombinant DNA Research* indicate the reason(s) why in the space provided. Please make sure to ***cite the regulation that constitutes the exemption within NIH Guidelines and paraphrase the regulation within your explanation***.

D. Will there be a petition to ***NIH for exemption*** from the guidelines?
_____YES _____NO

National Institutes of Health (NIH) Categories:

E. Please select the National Institutes of Health (NIH) category that accurately describes your experiment, *where applicable.*

NIH CLASS III-A:

Experiments that require Institutional Review Board (IRB) approval *before* the initiation of the experiment.

___ **III-A-1:** Deliberate transfer of a drug resistance trait to microorganisms that are known to

acquire it naturally, if such acquisition could compromise the use of the drug to control disease agents in human or veterinary medicine or agriculture.

___ **III-A-2:** Certain experiments involving the deliberate transfer of recombinant DNA or DNA or RNA derived from recombinant DNA into one or more human subjects.

NIH CLASS III-B:

Experiments that require NIH and IRB approval before the initiation of the experiment.

___**III-B-1:** Deliberate formation of recombinant DNA containing genes for the biosynthesis of toxin molecules lethal at an LD50 of less than 100 monograms per kilogram body weight (i.e., microbial toxins such as tetanus toxin).

___**III-B-2:** Accelerated Review of Human Gene Transfer Experiments.

___**III-B-3**: Minor Modifications to Human Gene Transfer Experiments.

CLASS III-C:

Experiments that require IRB approval before the initiation of the experiment.

___ **III-C-1:** Experiments using human or animal pathogens (Class 2, Class 3, Class 4, or Class 5 Agents) as host vector systems.

___ **III-C-1a:** Experiments involving the introduction of recombinant DNA into Class 2 agents carried out at bio-safety Level 2 containment.

___ **III-C-1b:** Experiments involving the introduction of recombinant DNA into Class 3 agents carried out at bio-safety Level 3 containment.

___ **III-C-2:** Experiments in which DNA from human or animal pathogens (Class 2, Class 3, Class 4, or Class 5 Agents) is cloned in nonpathogenic prokaryotic or lower eukaryotic host-vector systems.

___**III-C-2a:** Experiments in which DNA from Class 2 or Class 3 Agents is transferred into nonpathogenic prokaryotes or lower eukaryotes carried out at bio-safety Level 2 containment.

___ **III-C-3:** Experiments involving the use of infectious animal or plant DNA or RNA viruses in the presence helper virus in tissue culture systems.

___ **III-C-3a:** Experiments involving the use of infections Class 2 animal viruses in the presence of helper virus performed at bio-safety Level 2 containment.

___ **III-C-3b:** Experiments involving the use of infectious Class 3 animal viruses or defective Class 3 animal viruses in the presence of helper virus carried out at the bio-safety level containment.

___ **III-C-3c:** Experiments involving the use of infectious animal or plant viruses or defective animal or plant viruses in the presence of helper virus not covered by the above sections carried out at the bio-safety Level I containment.

F. Where will the project be carried out? *(i.e., Laboratory; Greenhouse or Animal Facility.)*

G. Are recombinant materials prepared or reconstituted at a location other than the administration site? **_____NO _____YES** (If **YES**, *address precautions regarding* ***transportation*** of the materials between the locations in the space provided.)

H. Is the goal of this research study to induce or enhance immune response in the study subjects? **_____NO _____YES** (If **Yes**, please ***describe the expected response***.)

I. Does this research project utilize recombinant DNA methodology (i*.e.,* Use of plasmids; retroviral vectors or other genetic constructs with Foreign DNA; Cell lines containing Foreign DNA; etc.)? *(Note: Answer* ***yes*** *even if the materials are obtained commercially or from a collaborator.)*
_____NO _____YES

J. Will this project require large-scale fermentation *(greater than (>) 10 liters)* of organisms containing recombinant DNA molecules? *Large scale (> 10 liters) requires special approval from the IRB.*
_____YES _____NO

K. Please provide a complete inventory of ALL Bio-safety Level 2 (BL2) ***agents*** currently located in the laboratory, or to be constructed in the proposed project.

NOTE: Include Vector name and type. If the source of the vector is a research group from another institution, provide the principal researcher's name and hosting institution. Describe the nature of inserted sequences (i.e., structural gene, etc.). Indicate the storage area and building where these items will be stored (i.e., liquid nitrogen tank, Room 200, Building F (Forbes).

Table I-101: Bio-safety Level 2 (BL2) Agents

VECTOR	SOURCE OR SUPPLIER NAME	EXPRESSED	GENE	PROMOTER/ENHANCER	PACKAGING	STORAGE	ARE THESE AGENTS CURRENTLY IN LAB?	DO YOU PLAN TO CONSTRUCT THESE AGENTS?
							__YES __NO	__YES __NO
							__YES __NO	__YES __NO
							__YES __NO	__YES __NO
							__YES __NO	__YES __NO
							__YES __NO	__YES __NO

L. List all BL2 ***reagents*** currently on hand or to be constructed **for use on this project** – i.e., viral vectors of any type, plasmids containing whole viral genomes, plasmids containing viral genes to be used for packaging, or stable cell lines containing any of these constructs.

Table I-102: Bio-safety Level 2 (BL2) Reagents

VECTOR	SOURCE OR SUPPLIER NAME	EXPRESSED	GENE	PROMOTER/ENHANCER	PACKAGING	STORAGE	ARE THESE REAGENTS CURRENTLY IN LAB?	DO YOU PLAN TO CONSTRUCT THESE REAGENTS?
							__YES __NO	__YES __NO
							__YES __NO	__YES __NO
							__YES __NO	__YES __NO
							__YES __NO	__YES __NO
							__YES __NO	__YES __NO

M. Please describe the constructs that you plan to create for this project in the space provided.

N. Will this project, at some point, require the release of organisms containing recombinant molecules into the environment?
_____YES _____NO

O. Is there any possibility that organisms containing recombinant molecules could enter the food chain*?*
_____YES _____NO

P. Will there be any attempt to transfer recombinant DNA molecules in vivo to plant or animal systems (other than tissue culture)?
_____YES _____NO

Q. Please list the personnel who will be working with the agents/reagents and specify all previous relevant recombinant DNA training and experience.

Names of personnel involved and Title or Position on the Research Team	Relevant recombinant DNA Experience including the Number of Years and recombinant DNA Training	Date when training was completed (MM/DD/YYYY)

R. In the space provided below, describe the procedures for responding to an accidental spill(s) and/or release(s).

S. Date of most recent Laboratory Safety Inspection: __/__/____
Please attach a copy of the most recent Lab Safety Certificate.

Cell Culture Experiments:

T. In the following table (Table T-101), list the primary cell line or culture to be infected. Include species and tissue of origin, name of cell line, and recombinant DNA source to be utilized. Indicate the source or supplier of the cells (i.e., commercial supplier, distribution from another institution's research group, etc). If the source of the vector is another institution's research group, provide the principal researcher's name and hosting institution.

Table T-101: Cell Lines or Cultures

Cells to be used (Primary culture or Cell line)	Cell Type	recombinant DNA Vector and Expressed gene	Source or Supplier

U. Will any recombinant DNA materials be administered to human subjects? (If **YES**, please describe the *number of human subjects* proposed to use in the research, the recombinant DNA *vector and expressed gene*, and the *amount and titer* in the space provided.

V. Will this project use viral vectors? **_____ NO _____ YES** (If **YES**, please answer the following questions.)

1. Are the viral vectors replication competent*?*
   _____YES *(Proceed to **Question 2**)* **_____NO** *(Proceed to **Question 3**)*
2. What is the known host range of the virus?
3. What specific method will be used to determine ***non-replication*** of viruses?

W. Will this project use constructs which include whole viral genomes? **_____ NO _____ YES** (If **YES**, please answer the following questions.)

1. Are the constructs replication competent*?*
   _____YES *(Proceed to **Question 2**)* **_____NO** *(Proceed to **Question 3**)*
2. What is the known host range of the virus?

3. What specific method will be used to determine ***non-replication*** of viruses?

Additional Attachments *(Checklist)*:

____Copy of principal investigator(s)' curriculum vitae attached ***(See the following CV Waiver Statement)***

____***CV Attached Waiver Principal Investigator:*** A copy of CV as an attachment can be waived if the principal investigator has previously submitted a copy of their CV within the last two years and that CV resides on file with the IRB, or the investigator is a student who is under the guidance of a faculty sponsor.

____Copy of all other investigator(s)' curriculum vitae attached ***(See the following CV Waiver Statement)***

____***CV Attached Waiver All Other Investigators:*** A copy of CV as an attachment can be waived if all other additional investigators have previously submitted a copy of their CV within the last two years and that CV(s) reside on file with the IRB, or the investigators are students who are under the guidance of a faculty sponsor.

Assurance of Principal Investigator:

I understand experiments involving laboratory animals are not to be conducted unless approved by the Thomas University Institutional Review Board on the issue Recombinant Deoxyribonucleic acid or Recombinant DNA in Research.

I agree to comply with and accept responsibility for the *specific and formal* training of my staff in all bio-safety *Level II Agents* that will be utilized within the laboratory. This formalized training will be *documented* and will include, but not be limited to, personal protective equipment (PPE), spill and release controls, and procedures to be use within the laboratory. All affected support staff must also be *notified and formally trained* concerning any bio-safety *Level II Agents*, and protective procedures to be utilized. This training will also be *documented*.

I agree to comply with the emergency procedures for cleaning spills involving recombinant DNA within the laboratory as described in the National Institutes of Health Laboratory Safety Monograph.

I agree to comply with the National Institutes of Health requirements pertaining to ***shipment, use and transfer*** of recombinant DNA materials. I am familiar with and agree to abide by the provisions of the current National Institutes of Health Guidelines, the policies of Thomas University, and the Thomas University Institutional Review Board's instructions pertaining to this project.

As the Principal Investigator on this project, I certify by my signature below that the information provided in this application is accurate and fully describes any and all procedures regarding Recombinant Deoxyribonucleic acid or Recombinant DNA under, which I will conduct this research.

I, the undersigned, agree to accept responsibility for my co-investigators and other personnel involved on this project, in regards to their compliance with the above stated policies.

I will retain the documentation of the experiment, experimental data, reports and all procedures performed for ***at least three years after*** the proposed activity has been completed or discontinued.

The IRB is obligated to continually review this activity. Therefore, I agree to furnish progress reports to the committee when requested.

I, the undersigned, understand and agree that ***upon approval of this application***, should complaint of a *violation of any procedures* as proposed within this document occur, as deemed through investigation by the Thomas University IRB or bodies employed by Thomas University, this application *will be reversed and denied continuation of approval, and the termination of the research under this proposal will be so ordered and enforced to the fullest extent of the law.*

Please note: Signature of this application form by the primary investigator provides written assurance that the primary investigator attests that they have read and understand all abovementioned statements concerning Thomas University policy for research or similar activities involving Recombinant Deoxyribonucleic acid or Recombinant DNA in research; federal, state and county regulations and laws where applicable; and certify that they will uphold all regulations and policies as required and prescribed by law, along with the National Institute of Health Recombinant DNA Guidelines, and the Thomas University policy as stated herein.

_____ _____

Principal Investigator's Signature (SEAL) ***Date***

For faculty supervisor approval:

I believe that the research can be safely completed and conducted within the bounds stated by the National Institutes of Health Recombinant DNA Guidelines. Furthermore, I have read the enclosed proposal, and I am willing to supervise the investigator(s).

_____ _____

Faculty Sponsor's Signature (SEAL) ***Date***

RESPONSE TO APPLICATION FOR APPROVAL OF RESEARCH INVOLVING RECOMBINANT DEOXYRIBONUCLEIC ACID OR RECOMBINANT DNA

All responses to research will be provided to the ***principal investigator*** in writing from the Thomas University Institutional Review Board. According to the complexity of the research, a response from the board (full review of application) may take up to, ***but not exceed,*** three weeks. Should further, appropriate review by officials of the institution be deemed necessary, it could delay a response from the Institutional Review Board for an additional two week period beyond the initial three week period. In addition, the request for an expedited review by the principal researcher ***does not exclude*** the possibility of a determination of a ***full committee review***. This is held at the discretion of the Institutional Review Board and its Chairperson. When at all possible

and should the research request exhibit those criteria that merit an expedited review that option ***will be exercised*** by the Institutional Review Board.

For questions, please contact the Thomas University IRB at irb@thomasu.edu.