Print Form

Mahidol University
Institutional Biosafety Committee

เลขที่รับ.....
วันที่รับ.....
Approval .No.....
Date of Approval. .....

Form-B

Section I. Administrative Information

Principal Investigator: ……...……

Address:……...Phone…….Fax:……

Lab Room (s) number.....

Faculty/Institute/Center…….....

E-mail Address: ……..……

Lab/Research Personnel Involved in this research:

……..……..

……

……

Section II Required Research Review and Training

1. Does your research involve <u>human blood, body fluids, tissues or organs</u>?

□ Yes □ No

<u>If yes,</u>

a) Has the project been reviewed and approved by the Human Research Committee?
□ Yes (Approval No……., date…….) □ No

b) Specimens collected or manipulated/used in lab:
□ Blood □ Serum □Feces □ Urine □ Semen □ Spinal fluid □ Saliva
□ Tissues/Organs □ Other……

c) Types of manipulation:
□ Centrifugation □ Pipetting □ Dissection □ Blending/mixing
□ Sonication □ Frozen Sections □ Flow Cytometry □ Fixed/preserved
□ Other……

2. Does your research involve <u>human or other mammalian cell in culture?</u>

□ Yes □ No

<u>If yes,</u>

a) What cell lines do you use? Please indicate whether they are of human or animal origin, and whether they are primary, secondary or immortalized cultures

……
……
……
……
……
……
……
……

b) Are you planning on immortalizing cell lines? □ Yes □ No

c) Will you use viral transformation? □ Yes □ No

If yes, specify:……

d) Will you transform cell lines with oncogenes in culture? □ Yes □ No

e) Will you use any of the following materials in cell culture?

□ Cytotoxic/chemotherapy agents
Specify ……..……
□ Toxins. Specify……...…….……..

3. Does your research involve <u>infectious or potentially infectious to humans or animals and toxic biological agents?</u>

□ Yes □ No

If yes,

a) Does your research involve the use of any of the following biological agents?

Bacteria	□Yes	□ No	Parasites	□Yes	□ No
Fungi	□Yes	□ No	*Viruses	□Yes	□ No (*excluding Phages)
Rickettsia	□Yes	□ No	Prions	□Yes	□ No

If yes, list each agent by species, strain/isolates, and risk group.
……
…..….....
.....

b) Is this organism already available in your laboratory or on campus? □Yes □ No

c) What is the largest volume of organisms used/produced? (liter or milliliter).……..…….

4. Will you conduct research involving selected toxins?

□ Yes □ No

If yes,

a) Is the toxin-producing organism inactivated prior to other lab manipulations?
□ Yes □ No

b) Specify methods of inactivation: □ Heat □ Chemical □ Radiation □ Other……...

If you concentrate the toxin-producing organism, specify methods of concentration:
……
…...……..……
…….....

5. Does your research involve the use of recombinant DNA? (This includes experiments involving transgenic rodents in which the animal's genome has been altered by stable introduction of rDNA, or DNA derived there from, into the germ line (transgenic rodents).

□ Yes □ No

If yes,

a) Recombinant Insert (Transgene):

1. Source(s) of DNA/RNA sequences (include species, gene name and abbreviation, ATCC No.)……..……

……

……

2. If the recombinant contains viral DNA, does the insert represent more than 2/3 of the viral genome? □ Yes □ No

3. Will the biological activity of the gene product or sequence inserted pose a hazard to humans or animals? □ Yes □ No

4. Will a deliberate attempt be made to obtain expression of *the foreign gene* encoded in the recombinant DNA? □ Yes □ No

5. Will your research include the deliberate formation of recombinant DNA that contains genes for the biosynthesis of toxin molecules? □ Yes □ No

6. Will you conduct experiments that will involve the deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally? □ Yes □ No

b) Vector

1. Identify the host strain (include species and strain) used for propagation of the recombinant:……..……..…
……..……

2. Is a vector (specific phage, plasmid or virus) required?

□ Yes □ No If yes, specify……..….

3. Is viral vector replication defective? □ Yes □ No

4. Is a helper virus required? □ Yes □ No If yes, specify:……..……

c) Others ……...……..……

6. Will animals be used with any biological agents listed in this application?

□ Yes □ No

If yes,

a) Are the animals transgenic? □ Yes □ No

b) Will you ship or receive any animal materials, blood, body fluids, tissues, or organs? □ Yes □ No

c) Has this research been approved by the Institutional Animal Care & Use Committee? □ Yes (IACUC Protocol No. & Approval Date……) □ No

7. Will radioisotopes be used to label any biological agents listed in this application?

□ Yes (Approved No……..…….date…….……) □ No

8. Describe how each biological agent, cell line, tissue, etc. will be used. Provide sufficient detail so that the MU-IBC can evaluate your activities.

9. If the organism is infectious, is there a <u>vaccine available to research staff?</u>

□ Yes □ No

10. Have you and the personnel listed above received <u>biological lab safety training?</u>

□ Yes □ No

<u>If yes,</u> attach the training document.

11. Have you safety operation procedure (SOP)?

□ Yes □ No

<u>If yes,</u> attach the SOP

12. Have you attached a Biohazard Control Plan?

Note: For research that involves Risk Group 2 agents, the "Biohazard Control Plan" must be provided to assure adequate protection of employees, students, the community, and the environment.

□ Yes □ No

13. Exposure determination

1. List who will be working with biological agents, animals, or hazardous material (by name & job title). It is recommended that all lab personnel receive information about the risks associated with any research involving infectious agents. This is especially recommended for lab personnel who may be immune-compromised.

2. Describe the general types of experimental procedures that will be performed (e.g. cell culture, protein purification, drawing blood, *etc*).

14. Control methods:

1. Describe facility in which work is to be performed.

2. Describe who will have access to the facility and how access will be controlled?

3. How and when will facility be cleaned and decontaminated? Will Facilities Management custodial personnel have routine access, and if so, how will they be protected from hazardous materials?

4. Describe safety devices that will be used. These may include some or all of the following: biosafety cabinets, hand washing facilities, mechanical pipetting devices, puncture resistant sharps containers, splash guards, self-sheathing needles.

5. What types of personal protective equipment will be used (gloves, masks, lab coats, etc). How will the equipment be decontaminated, laundered, or disposed of?

6. <u>Vaccination</u>: Will it be necessary to vaccinate workers against infectious agents? If so, describe plans for vaccinations.

7. <u>Accidents</u>: What procedures will be followed in case of an accident?

8. Waste disposal: Describe provisions for disposal of hazardous materials. If all or part of hazardous material is to be decontaminated on site, specify procedures to be used.

9. Labeling: Describe tags, labels, or bags that will be used to identify hazardous materials. If hazardous material is to be decontaminated on site, specify how material will be labeled to indicate that it is no longer infectious.

10. Training: Describe how workers will be trained for biological lab safety and handle all hazardous materials (biological, chemical and radioactive).

15. Others, if any ……..

I acknowledge all requirements and restrictions of the most current TBC guidelines for the Biosafety Level authorized by the IBC. I accept responsibility for the safe conduct of the experiments conducted at this Biosafety Level. I understand that it is my responsibility to assure that all personnel working in my laboratory with any of these hazards are fully informed about their specific dangers, proper actions for safe use and steps to take in case of accidents, and are provided with all necessary safety equipment and instructions in its use. I will contact the MUIBC/Faculty IBC immediately following any adverse event that leads to an accidental exposure to any biological agents listed in this form that may be harmful to humans or animals.

_____ _____

Date Signature of Principal Investigator

PLEASE FILL OUT THE FORM BY ANSWERING ALL SECTIONS APPLICABLE TO THE PROJECT. Attach additional pages if necessary.