



Chulalongkorn University
Institutional Biosafety Committee

Receiving No.....
Receiving date.....
Approval No.....
Approval date.....

Form B

A Form to Request an Approval from
the Institutional Biosafety Committee of Chulalongkorn University

Please fill out the form by answering all sections applicable to the project.

Attach additional pages if necessary.

Section I Administrative Information

1. Project title:

(Eng).....

(Thai).....

Subproject title (If different from the project title):

(Eng).....

(Thai).....

2. Principal investigator of the project:

Name-Surname:..... Degree:..... Position:.....

Principal investigator of the subproject (If different from principal investigator of the sub project):

Name-Surname:..... Degree:..... Position:.....

3. Lab/research personnel involved in this research (Personnel are related to biological work.):

Name-Surname:..... Degree:..... Position:.....

Name-Surname:..... Degree:..... Position:.....

Name-Surname:..... Degree:..... Position:.....

Name-Surname:..... Degree:..... Position:.....

Name-Surname:..... Degree:..... Position:.....

4. Contacting address:.....

Telephone:..... Mobile phone:.....

Fax:..... E-mail address:.....

5. Funding support:.....

Submitted Approved

6. Project duration:..... Start date:..... End date:.....

(Please attach the full research proposal and highlight in the part of research proposal related to biological work.)

Section II Required Research Review and Training

1. Risk group (refer to the levels of risk in pathogens and animal toxins list in Pathogens and Animal Toxins Act, B.E.2558) (download <http://www.ibt.research.chula.ac.th>):

Pathogen: Risk group 1 Risk group 2 Risk group 3 Risk group 4

Animal toxin: Risk group 1 Risk group 2 Risk group 3

In case it is not controlled by Pathogens and Animal Toxins Act, B.E.2558, please explain.

Agent/material..... Risk group/LD₅₀..... Reference of risk group/LD₅₀.....

2. Biocontainment level (refer to the biocontainment levels in Pathogens and Animal Toxins Act, B.E.2558 and Biosafety Guidelines for Modern Biotechnology BIOTEC, 2016):

Biosafety level 1 Biosafety level 2 Biosafety level 2 enhanced

Biosafety level 3 Biosafety level 4

Laboratory room number/floor/building.....Biosafety level.....

Laboratory room number/floor/building.....Biosafety level.....

Laboratory room number/floor/building.....Biosafety level.....

Laboratory room number/floor/building.....Biosafety level.....

3. Does your research involve human or animal blood, body fluids, tissues or organs?

Yes No

Human specimens Animal specimens

If yes,

a) Has the project been reviewed and approved by the Human Research Committee or IACUC?

Yes (Approval No....., date.....) In progress No

b) Specimens collected or manipulated/used in lab:

Blood Serum Feces Urine

Semen Spinal fluid Saliva Tissues/organs

Others.....

c) Types of manipulation:

- Centrifugation Pipetting Dissection Blending/mixing
 Sonication Frozen sections Flow cytometry Fixed/preserved
 Others.....

4. Does your research involve human or other mammalian cell culture?

- Yes No

If yes,

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.

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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.....

5. Does your research involve infectious or potentially infectious (level 2 or above) to humans or animals, animal toxins or biological toxins?

- 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

Others.....

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

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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).....

6. Will you conduct research involving animal toxins or biological 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 Others.....

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

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7. 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.)

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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:

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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.....

8. 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.....) In progress No

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

Yes No

If yes,

Yes (Approved No.....date.....) In progress No

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

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11. If the organism is infectious, is there a vaccine available?

Yes No

12. Have you and the personnel listed above received biological lab safety training?

Yes No

If yes, attach the training document.

13. Is there a safety operation procedure (SOP) existed to the procedure?

Yes No

If yes, attach the SOP.

14. 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.

a) 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.

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

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b) Control methods

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

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

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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?

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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.

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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?

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

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7. Accidents: What procedures will be followed in case of an accident?

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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.

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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.

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

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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 CU-IBC/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.

Signature

Date

(.....)

Principal investigator of the project

Signature

Date

(.....)

Principal investigator of the subproject

Signature

Date

(.....)

Head of Department

Adapted from Mahidol University (by permission)

Updated 19/03/2020