 **Memorandum**

IBC-02

**Department**:………………………………………….……..… **Tel:**...............................................

**Ref:** …………………………………/…………………………….. **Date:** ………….………………

**Subject:** Research Proposal for Biosafety Assessment

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**To:** Chairperson of Institution Biosafety Committee

My name is \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. I am (Position) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_at [Dept. / Affiliation] \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. I would like to submit the research proposal entitled “\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_” for Biosafety assessment approval and I have attached one (1) copy of each document as follows:

|  |  |  |
| --- | --- | --- |
| List of Documents | Yes | No |
| 1. Biosafety Risk Assessment Form, IBC-02 Form |  |  |
| 1. Biosafety Self-Inspection Checklist, IBC-03 Form\* |  |  |
| 1. Research Proposal/Complete Activity |  |  |
| 1. Certificate of Attendance in Biosafety Risk Assessment training of the Principal Investigator (PI), Co-Principal Investigator (Co-PI) and/or the advisor |  |  |
| 1. Fact Sheet or MATERIAL SAFETY DATA SHEET (MSDS) of microorganism or biological biosafety substance used in the research |  |  |
| 1. Evaluation of the Project/THESIS Proposal Examination\*\* |  |  |
| 1. CD/DVD record of research project mentioned in items 1-6 in PDF and Word Format |  |  |

Signature …………….…………………….

(………………………………………….)

Principal Investigator/Student

Signature …………………………………......

(………………………………………….)

Head of Department/Program Director/Advisor

|  |  |
| --- | --- |
| Principal Investigator |  |
| Affiliation/Contact | Telephone: |
| Email: | Fax: |
| Project title: |  |
|  |
| Grant: |  |
| Duration: | From: To: |
| Co-Principal Investigator: |  |
| Objectives: |  |
|  |
|  |

**Please 🗹 any item that applies to your project and attach a project proposal for consideration.**

1. **Types of organisms used in the research**

🞎 Microorganism (Bacteria/Yeast/Fungi/Viruses) 🞎 Plant……………………….. 🞎 Animal………………….

🞎 Biological substance…………………………... 🞎 Others………………………

**2. Working volume per batch**

🞎 Lab scale (less than 10 liters or 10 kilograms) 🞎 Glass house (for plant)

🞎 Pilot scale (more than 10 liters or 10 kilograms) 🞎 On-site

**3. Research category**

🞎 Class 1 Non-pathogens:

(1) Research and genetic engineering experiment involving non-pathogens or genes that may cause disease in humans or plants, or genetic toxins (refer to the levels of risk in pathogens and animal toxins list).

(2) Research and experiment involving non-pathogens or genes for humans or plants, or genetic toxins e.g. microorganism in Risk group 1, weed or non-carrier animal.

(3) Research and experiment involving biological substance that is not harmful/contaminated e.g. genetic substance, non-pathogens or toxicity, humus, carcass, soil sample, sludge from nature or factories or waste treatment system that is non-pathogen or toxin.

🞎 Class II Low-Moderate risk pathogens)

(1) Research and genetic engineering experiment involving pathogens that may cause disease for humans, plants, or animals, or genetic toxins that cause low risk to individuals, a community or the environment.

(2) Research and experiment that use microorganisms that are likely to cause disease in humans, plants or animals (refer to the levels of risk in pathogens and animal toxins).

(3) Research and experiment involving biological substance related to pathogen, cancer pathogen or toxin (toxin LD50 higher than 100 nanogram/kilogram) e.g. extract or toxin from pathogen, fresh garbage, dung, bio-fertilizer or medical leftover e.g. blood, tissue or mucus that may cause disease, or soil or water sample or sludge from nature or factories or waste treatment system that is contaminated and toxic.

🞎 Class III High risk pathogens: Research and experiment involving high risk to community officials and environment, or causing danger at an unknown level must request for Biosafety assessment approval from the Technical Biosafety Committee (TBC) (propose the project through Institutional Biosafety Committee).

(1) Genetic engineering research that might be harmful to the investigators, community and environment or involving treatment with genetic modification with high risk or unknown risk.

(2) Research involving pathogens that my cause serious disease in humans, plants or animals (therapeutic and vaccination) as well as the environment.

(3) Research and experiment involving biological substance related to pathogen, cancer pathogen or toxin (toxin LD50 higher than 100 nanogram/kilogram; See Toxin samples in Appendix 1) or unknown substance or unknown status e.g. toxin from microorganisms, soil, water or garbage, feces, tissue or mucus that contain serious disease pathogens or toxin, etc.

**4. Details of organism or biological substance**

4.1 Research using GMO technology (please attach relevant plasmid for consideration)

|  |  |
| --- | --- |
| Genetically modified organism |  |
| Expression of genes that are expected |  |
| Host, please specify the strain |  |
| Target gene and donor |  |
| Vector |  |
| Marker |  |
| Reporter |  |
| Risk group | Please specify ………………………………………………….  🞎 Risk group 1 🞎 Risk group 2 🞎 Risk group 3 🞎 Risk group 4 |
| Biosafety level | 🞎 BSL 1 🞎 BSL 2 🞎 BSL 3 🞎 BSL 4 |

**4.2 Microbe Pathogen and Non-pathogen (please attach safety use of organisms)**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Type | Scientific name | Strains/isolates | Sources | Risk group | BSL |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
| Type of infectious agents: P: Parasite F: Fungi B: Bacteria Y: Yeasts R: Rickettsia A: Arbovirus T: Toxin PR: Prions VR: Viroid O: Others | | | | | |
| Infectious agents (pathogen) | | | 🞎 Human 🞎 Animal 🞎 Plant | | |
| Infectious agents(resistance to antibiotics) | | | 🞎 Yes ………. 🞎 No | | |
| In vitro (if Yes, please specify) | | | 🞎 Research in vitro in Medium  🞎 Research in vitro in Organ  🞎 Research in vitro in Cell culture | | |
| In vivo (if Yes, please specify) | | | 🞎 Research in vivo in Vertebrate  🞎 Research in vivo in Plant  🞎 Research in vivo in Invertebrate | | |

**4.3 Biological substance Pathogen and Non-pathogen**

|  |  |  |  |
| --- | --- | --- | --- |
| **Bio-substance/sample** | **Sources** | **Risk group** | **Cell culture (Y/N)** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

**4.4 Plants, including algal and mushroom**

|  |  |  |  |
| --- | --- | --- | --- |
| **Types** | **Plant part** | **Quantity/Volume** | **Source** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

**5. Laboratory: Type of laboratory 🞎 BSL 1 🞎 BSL 2 🞎 BSL 3 🞎 BSL 4**

|  |  |
| --- | --- |
| 🞎 BSL 1 |  |
| 🞎 BSL 2 |  |
| 🞎 BSL 3-4 |  |

**6. Detail of biosafety inspection**

6.1 Laboratory equipment (be able to specify maintenance procedure efficiently)

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6.2 Measures of preventing contaminant into the environment (controlling contaminants procedure practice)

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6.3 Disinfection and decontamination (be able to specify decontamination and disposal methods)

**7. PPE and Safety equipment**

|  |
| --- |
| 7.1 Personnel Protective Equipment  🞎 Lab Coat 🞎 Gloves 🞎 Safety Glass  🞎 Respirator /Mask 🞎 Others …………………………………. |
| 7.2 BSC/Autoclave  🞎 Biosafety Cabinet Class I 🞎 Class IIA 🞎 Class IIB1 🞎 Class IIB2 Date of inspection ………..  🞎 Autoclave, Date of inspection ………. 🞎 others …………………………………. |
| 7.3 Safety management  🞎 Washing soap and sink in the Labs 🞎 Biohazard Signs  🞎 Access control with key 🞎 Biosafety Spill Kit  🞎 Name of Authorized person and Emergency Call 🞎 Others …………………………………….. |

**8. Training Record**

|  |  |  |  |
| --- | --- | --- | --- |
| **Name-Last Name** | **Responsivity** | | **Certificate of Biosafety Training** |
|  |  | |  |
|  |  | |  |
| Signature ……………………...……………….  Principal Investigator (………………………….)  Date: ………………………………………….. | | Signature ……………………...……………….  Dean/Director (…………………………….….)  Date: ………………………………………….. | |

**For Biosafety Secretary**

Research Category 🞎 Category 1 🞎 Category 2 🞎 Category 3

Type of Laboratory 🞎 BSL 1 🞎 BSL 2 🞎 BSL 3 🞎 BSL 4

Please process as follows:

🞎 Approved without any amendments and inform IBC

🞎 Approved in principle, but the investigators must explain/amend………………………………

🞎 Proposed for IBC Assessment

Signature ……………………………………… (Secretary, IBC) Date: …………...…………….

(……………………………………………….)

**For Biosafety Committee**

Research Category 🞎 Category 1 🞎 Category 2 🞎 Category 3

Type of Laboratory 🞎 BSL 1 🞎 BSL 2 🞎 BSL 3 🞎 BSL 4

🞎 Approved without any amendments ~~and inform IBC~~

🞎 Approved in principle, but the investigators must explain/amend………………………………

🞎 Rejected because ………………………………………………………………………………..

Opinion given dated on: …………………….……...…………….

**For Biosafety Chairperson**

Research Category 🞎 Category 1 🞎 Category 2 🞎 Category 3

Type of Laboratory 🞎 BSL 1 🞎 BSL 2 🞎 BSL 3 🞎 BSL 4

Proposed to carry out as follows:

🞎 Approved without any amendments ~~and inform IBC~~

🞎 Approved in principle, but the investigators must explain/amend………………………………

🞎 Rejected because ………………………………………………………………………………..

🞎 Proposed to TBC for Biosafety Assessment

Signature ……………………………………… (IBC Chair) Date: …………...…………….

(……………………………………………….)