 **Memorandum**

IBC-02

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

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

**Subject**: Research Proposal for Biosafety Assessment

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**To:** Chairperson of Institution Biosafety Committee

I, ………………………..............................……, …………………........................…… (position) from the.........................................................…… (Faculty/Institution/Department) would like to submit a research proposal entitled (Thai and English) ………………………….…………………for Biosafety Assessment approval and I have attached a copy of each document as follows:

|  |  |  |  |
| --- | --- | --- | --- |
|  | List of Documents | Yes | No |
| 1 | Biosafety Risk Assessment Form, IBC-02 Form |  |  |
| 2 | Research Proposal/Thesis proposal |  |  |
| 3 | Work flow describing experimental procedures related the use of biomaterial |  |  |
| 4 | Certificate of Attendance in Biosafety Risk Assessment training of the Principal  Investigator (PI), Co-Principal Investigator (Co-PI), and/or the advisor\* |  |  |
| 5 | Biological safety data sheet of biomaterial used in the research (e.g., Safety data sheet or Pathogen safety data sheet of Doner and Host and plasmid map) |  |  |
| 6 | Project/Thesis Proposal Examination Document\*\* |  |  |
| 7 | Certificate of registration of pathogens and animal toxins issued by Department of Medical Science, Ministry of Public health\*\*\* |  |  |

\*In case of a student submitting thesis proposal for biosafety assessment, both student’s and advisor’s certificates must be attached.

\*\*Please submit Research/Thesis/Dissertation Proposal Examination Document (only for students’ projects).

\*\*\*Please submit the certificate of registration of pathogens and animal toxin, if the research is classified as Risk Group 2

Signature …………….…………………….

(………………………………………….)

Principal Investigator/Student

Date ………………. /………/……………….

Signature …………………………………......

(………………………………………….)

Head of Department/Program Director/Advisor

Date ………………. /………/……………….

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Principal Investigator  (In the case of student, insert advisor’s as PI) |  | | | | | | |
| Affiliation/Contact |  | | | Tel. | |  | |
| E-mail |  | | | Fax. | |  | |
| Student |  | | | Tel. | |  | |
| Project title | (Thai) | | | | | | |
| (English) | | | | | | |
| Grant |  | | | | | | |
| Duration time |  | From |  | | To | |  |
| Co-Principal Investigator | Full name ………………………Tel. ..........................E-mail........................  Full name ………………………Tel. ..........................E-mail........................  Full name ………………………Tel. ..........................E-mail........................  Full name ………………………Tel. ..........................E-mail........................  Full name ………………………Tel. ..........................E-mail.......................  Full name ………………………Tel. ..........................E-mail.......................  Full name ………………………Tel. ..........................E-mail....................... | | | | | | |
| Objectives |  | | | | | | |
|  | | | | | | |
|  | | | | | | |

**Please insert 🗹 in following boxes corresponding to your project information and attach a copy of the complete research proposal.**

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

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

🞎 Biological materials or samples…………………………... 🞎 Others………………………………………

**2. Amount of organisms or biological materials to be used in the research project per research cycle**.

🞎 Lab scale (less than 10 L or 10 kg) 🞎 Glasshouse level (for plant)

🞎 Pilot plant (more than 10 L or 10 kg) 🞎 Field testing

**3. Research Classification**

🞎 Class 1 Non-pathogens:

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

(2) Research and experiment using non-pathogens or genes that cannot cause disease on humans or plants, or genetic toxins, e.g. microorganisms in Risk Group 1, non-weed plants, or non-carrier animal.

(3) Research and experiment using a biological material that is not harmful/contaminated, e.g. genetic substance extracted from non-pathogens or non-toxicity, humus, carcass, soil and water samples or sludge from natural sources or factories or waste treatment system that is not contained pathogen or toxin.

🞎 Class II Low-Moderate risk pathogens:

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

(2) Research and experiment using microorganisms that probably are pathogen and may cause disease in humans, plants, or animals (referred to the levels of risk in pathogens and animal toxins).

(3) Research and the experiment using biological materials related to the pathogen, carcinogen, or toxin (LD50 higher than 100 ng/kg), e.g. extract or toxin from the pathogen, fresh garbage, dung, bio-fertilizer, or medical samples, e.g., blood, tissue or secretions that may contain pathogen, or soil or water samples or sludge from natural sources or factories or waste treatment system that is contaminated pathogen and toxin.

🞎 Class III High-risk pathogens: Research and experiment involving high risk to community officials and the environment or causing an unknown level hazard

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

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

(3) Research and experiment involving biological materials related to the pathogen, carcinogens or toxin (LD50 higher than 100 ng/kg according to Toxin samples in Appendix 1) or unknown substance or unknown status, e.g. toxin from organisms, soil and water samples or garbage, feces, tissue, or secretions that is contaminated dangerous pathogens and toxin.

(4) Research and experiments involving the development of microbial strains harboring multiple antibiotic resistance genes, where the antibiotics concerned are still in use for the treatment of humans, animals, or in agriculture

**4. Details of the organism or biological materials/samples**

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

|  |  |
| --- | --- |
| Genetically modified organism |  |
| Gene/product expression |  |
| Host, please specify the strain |  |
| Target gene and donor |  |
| Vector |  |
| Marker |  |
| Reporter |  |
| Gene transfer methods (please specify) |  |
| Risk group | Please specify ………………………………………………….  🞎 Risk Group 1 🞎 Risk Group 2 🞎 Risk Group 3 |
| Biosafety level | 🞎 BSL 1 🞎 BSL 2 🞎 GILSP 🞎 LS1 🞎 LS2  Others…………………………………………………………. |

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Type | Scientific name | Strains/Isolates | Sources | Risk group | BSL |
|  |  |  |  |  |  |
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|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
| 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 Pathogenic and Non-pathogenic biological materials/samples**

|  |  |  |  |
| --- | --- | --- | --- |
| **Bio-material/sample** | **Sources** | **Risk group** | Is there an additional culture? **(Y/N)** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

**4.4 Plants, including algal and mushroom**

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

**5. Work flow describing experimental procedures for the biological materials/samples**

**…………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………**

**6. Biosafety level of Laboratory: (If the laboratory has passed the certification inspection, please attach the laboratory certification)**

|  |  |  |
| --- | --- | --- |
| 🞎 Laboratory BSL 1 | (Room No./Building) | Certified on……… 🞎 Not certified |
| 🞎 Laboratory BSL 2 | (Room No./Building) | Certified on……… 🞎 Not certified |
| 🞎 Pilot plant GILSP/LS.... | (Room No./Building) | Certified on……… 🞎 Not certified |
| 🞎 Greenhouse | (Room No./Building) | Certified on……… 🞎 Not certified |

**7. Biosafety control and Mitigation**

**7.1** Engineering control and managements/Equipment

􀂅 Biosafety Cabinet (BSC) 􀂅 Class I 􀂅 Class II A1 􀂅 Class II A2 􀂅 Class II B1 􀂅 Class II B2 performance checks dated on……………………………

􀂅 Autoclave performance checks dated on......................

􀂅 Door and Window Closed preventing insects

􀂅 Other

􀂅 Soap and hand washing sink

**7.2** Administrative control and Management

􀂅 Biological signs

􀂅 Procedure for preventing environmental contamination

􀂅 Researcher held biosafety training certificate

􀂅 Biosafety spill kits

􀂅 Emergency call

􀂅 Other

**7.3** Standard Operation Procedures

􀂅 Good microbiological practices

􀂅 Biological spill response

􀂅 Decontamination and waste management

􀂅 Packaging and transportation

􀂅 Other

7.4 Personal protective equipment

􀂅 Lab gown

􀂅 Gloves

􀂅 Safety glasses

􀂅 Respirator/Mask

􀂅 Lab shoe/Shoe cover

􀂅 Other

**8. Training Record (Attach the training completion document)**

|  |  |  |  |
| --- | --- | --- | --- |
| **Name-Last Name** | **Responsibility** | | **Certificate of Biosafety Training** |
|  |  | |  |
|  |  | |  |
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|  |  | |  |
|  |  | |  |
| Signature ……………………...……………….  Principal Investigator (………………………….)  Date: …………/…………………/…………….. | | Signature ……………………...……………….  Lab supervisor\* (…………………………….….)  Date: ……………/……………………/……….. | |

**\*In case there is no Lab supervisor, Head of department may certified**