PROJECT INFORMATION FOR INSTITUTIONAL BIOSAFETY CLEARENCE

*[Please fill up separate sheet for each project in the prescribed proforma and submit **one hard copy & one soft copy (email)** of each. One both-sided printed copy of research proposal/thesis protocol to be attached along with a covering letter from PI. Please ensure that the hard copies are duly signed by PI]*

1. Name and Designation of the PI:

   Department:

   Mobile:

   Email id:

2. Year of joining AIIMS Kalyani:

3. Broad area of work- (ex., Infectious diseases, Malignancy, Complex diseases, etc):

4. Whether applying for an on-going project/proposal:

5. If on-going, what is the source of funding and duration of the project:

6. If this is in initial proposal, then which funding agency will this be submitted and when will it be submitted (approximately) and what will be its duration:

7. Does the funding agency require a formal biosafety compliance certificate from AIIMS Kalyani IBSC?

8. Relevant details of the project:
   - Title:
   - Objective(s) of the study:
   - Key words:
   - Work plan: in flow chart form with brief description (max. 3 pages)
   - Diagrammatic representation of recombinant DNA molecules to be used and constructed

9. Provide the following information (use additional sheet if needed):

(A) List lab personnel involved with this work (This list has to be submitted to DBT every year)

(B) Provide information (methodology) pertaining to the potential biosafety issues. Identify the types of potentially hazardous biological materials you plan to use: rDNA, including transgenic

animals; infectious agents; biological toxins; materials derived from human sources; and/or materials derived from animal sources

(C) Describe any administration of these potentially hazardous biological materials to any subjects (animal):

(D) Details of similar study done in any other National/ International Institute:

Provide sufficient details in the application describing all pertinent details regarding potential biosafety issues in your work so that the IBSC members can understand the biosafety issues clearly. If something is not clear, IBSC shall seek additional clarity and will result inadvertent delay in processing your application.

Indicate as 'NA' if the topic/question does not concern your PROPOSAL/PROJECT

Biosafety questions/issues arising due to infectious agents (IAs) originating from human bio-specimen samples and/or cell lines both in those obtained from outside AIIMS Kalyani

a) Do you collect bio-specimens from human patients/subjects?

b) If YES, what type of bio-specimen:

c) Does the sample arise from a patient suffering from an infectious disease? If YES then which disease, how it was diagnosed, whether the sample is suspected to have high titers of the pathogen:

d) Was the subject/patient subjected to any molecular tests to rule out blood-borne diseases before you collected his/her bio-specimen? If YES, then what tests:

e) In your assessment what are the potential IAs your sample may be carrying and what is the best way to prevent their transmission once your sample/bio-specimen is inside AIIMS Kalyani:

f) How is the sample shipped? (Please provide the name, details and signature of designated person responsible for transfer (both dispatch and receiving) of bio-

specimen) and whether it is done by the concerned Institute or outsourced to a private agency with details.

g) Do you keep permanent records describing source and nature of samples?

h) Do you know if the samples have been confirmed positive for any Infectious Agents that needs a biocontainment level above II (described in CDC guidelines for Biosafety in Microbiological and Biomedical Laboratories, contact the IBSC if you need a copy)?

i) Is Ethics approval obtained for this proposal/project?

j) What will you do with the bio-specimen? (culture/serology/microscopy/molecular analysis/others)-please specify separately for each type of bio-specimen

k) How will you process the bio-specimen? (Elaborate on the protocol to be followed for taking necessary biosafety precautions)

l) What is the level of biocontainment recommended while working with these cells/ infectious agents (described in CDC guidelines for Biosafety in Microbiological and Biomedical Laboratories, contact the IBSC if you need a copy)?

m) Does your procedure generate aerosols from the bio-specimen before treating it with denaturing agents?

n) If YES, then you should carry out the procedure within a Biosafety Cabinet Will you comply/already complied. Explain

o) Does your work involve primary or established cell lines? If YES which ones and what are the potential infectious agents, these cells may be harboring:

p) How will you ensure biosafety while working with these cell lines/ infectious agents?

q) What is the kind of waste generated from your experiments and how will they be disposed? (Please provide the name, details and signature of designated person responsible)

r) Are proper records maintained for each human bio-specimen sample received with details of its source, potential for transmitting an IA, how the sample is processed and how waste is disposed?

Biosafety questions/issues arising due to research on infectious agents (IAs) cultured/grown in the labs at AIIMS Kalyani

a) What IA are you working with?

b) What form is the starting material of the agent in (Ex. DNA, RNA, whole organism, cell line):

c) How will you culture/grow this agent, (which lab)?

d) What level of biocontainment is prescribed in the CDC guidelines to culture/grow this agent (CDC guidelines for Biosafety in Microbiological and Biomedical Laboratories, contact the IBSC if you need a copy)?

e) How will you comply with this requirement?

f) Briefly describe what you will do with grown/cultured agent:

g) What is the Biosafety concern(s) in this experiment (s)?

h) How will you deal with the concern (s)?

i) Is there a chance that the agent may escape to the environment?

j) If YES, how will you deal with it:

Biosafety questions/issues arising due to genetically modified organisms (GMOs)/living modified organisms (LMOs) –

a) Does your proposal/project involve work with GMOs/LMOs:

b) If YES, which ones:

c) What will you do with the GMO/LMO (describe in some detail the experiment):

d) What is the biosafety concern in this experiment (s)?

e) How you will deal with the issue(s):

f) Is there a chance that the GMO/LMO will be released in the environment?

g) If YES, then what precaution is taken/will be taken:

Biosafety questions/issues arising due to rDNA materials –

a) Does your proposal/project involve rDNA material:

b) If YES, describe in brief about the material:

c) What will you do with the rDNA material:

d) What is the biosafety concern in this experiment(s):

e) How you will deal with the issue(s):

f) If the rDNA material is released in the environment, what is the potential biosafety concern and how you will prevent that:

10. **<u>Methods adopted for personnel protection:</u>**

i. Plan for Vaccination and other prophylactic measures (if available for the organism(s) handled)

ii. List of medical examinations to be carried out – initially and periodic

iii. Nature of orientation training to be provided to lab personnel for handling, storage and disposal of bio-hazardous material

iv. Name, contact details and consent of the person responsible for the training with justification how the person is suitable for such responsibility.
Signature of the designated person _____

v. Name, contact details and consent of the person responsible for maintenance, disposal and upkeep of the lab along with record keeping of instruments, culture facility and disposal involving bio-hazardous material throughout the project duration **(The name and contact details of this person to be displayed prominently at the entry of the lab)**
Signature of the designated person _____

vi. Certified by PI that the financial expenses for prophylaxis/vaccination (if applicable), routine initial and periodic medical examination and treatment in case of exposure will be met by/from _____

vii. Certified by PI that appropriate Biohazard sign will be/is displayed prominently at the entry of the facility _____

11. **<u>Specific disposal and decontamination methods</u>** to be used for different bio-hazardous material to be generated in the project
Names of bio-hazardous materials and methods for decontamination (Autoclave; Disinfectants and chemicals (pl. specify); Incinerator:
Water-proof & chemical resistant bench tops: Available/ Not available
Sink for hand wash in each laboratory: Available/ Not available

12. Specific methods to be adopted for handling and disposal of hazardous chemical waste (Ethidium Bromide/Phenol/Toluene/Any other (pl. specify))

13. Import/Exchange of material within and outside the country (Please fill up separate sheet for each material)
Date of approval (RCGB/IBSC/HMSC):

Specimen description:

Quantity approved:

Date of Import/Exchange:

Status:

DECLARATION

I hereby confirm that I have provided the details in this application, to the best of my knowledge, and with full commitment to safeguard the biosafety of both the human personnel and the environment while executing this proposal/project.

Principal Investigator (Signature and Date with Seal)