**APPLICATION FOR EVALUATION OF PROPOSED/ONGOING PROJECTS FOR BIOSAFETY COMPLIANCE**

**Important Note:**

* Use separate sheets if required
* Indicate NA if not applicable
* Carefully read the below-mentioned points and answer them accordingly
* After filling up the form, the applicant must approve it from his/her HOD and forward this to the IBSC member secretory as a hard copy

1. Name of the Applicant : Designation :

Department :

Address :

Telephone No. :

Email :

1. Year of joining SNU, Kolkata:
2. Broad area of work:
3. Whether applying for an approved/ongoing/proposed project:
4. Does the funding agency require a formal biosafety compliance certificate from SNU-IBSC:
5. If ongoing, mention the source of funding and duration of the project:
6. Title of the approved/ongoing/proposed project with a brief overview:
7. Objectives of the project proposal:
8. Whether the use of any genetically engineered organisms (including plants and animals) is employed in the research proposal.

If Yes, then answer the following:

* 1. Description of Genetically engineered organisms
  2. Description of the target gene and mode of action.
  3. Description of the other genes inserted, if any (Such as marker/reporter gene)
  4. History of use including toxicity and allergenicity aspects:

1. Details on (Nucleic acid(s) & Vectors).
   1. Source of nucleic acid(s):
   2. Copy number of gene(s):
   3. Nucleic acid sequence (Please enclose the nucleic acid sequence map of the target gene):
   4. Vector(s) Description (Please enclose the map of the vector gene):
2. Summary of the proposed work plan with a timeline.
   1. Basic transformation work and tissue culture procedure at the laboratory level and standardize the procedure to assess the expression of the target gene in the transformed material:
   2. Transfer of target gene imported/ indigenously isolated in Indian germplasm and to assess the expression of the target gene in the transformed material:
   3. Transfer of target gene from imported materials such as seeds to indigenous species (by backcrossing) and to assess the expression of the target gene in the transformed material:
3. Anticipated new characters (including morphological and phenotypic changes) in GMOs/LMOs and product(s) thereof and expected difference as compared to conventional counterparts:
4. Briefly explain besides answering the pertinent questions in the questionnaire below, in your own words the nature of the work keeping in view the biosafety issues involved.
   1. Brief outline of the proposed work:
   2. Category(ies) [Biosafety level(s)] of experiments to be performed:
   3. Which lab will this procedure be carried out in:
   4. What is the kind of waste generated from your experiments and how will they be disposed of:
   5. What precautions will be taken to prevent any unintended dispersal of the HMOs, GMOs/LMOs and product(s) thereof?
   6. Contingency plan and risk management measures in case of an unintentional release of the HMOs, GMOs/LMOs and product(s) thereof:
   7. Proposed fate of the HMOs, GMOs/LMOs and product(s) thereof:
   8. Do you have any plan to collect bio-specimens from human patients/subjects:
   9. If YES what type of bio-specimen:
   10. Does the sample arise from a patient suffering from an infectious disease? If YES then which disease, how it was diagnosed, and whether the sample suspected to have high titers of the pathogen:
   11. 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:
   12. In your assessment what are the potential infectious agents (IAs) your sample may be carrying and what is the best way to prevent their transmission once your sample/bio-specimen is inside the SNU labs:
   13. How is the sample shipped and handled once inside the lab (give as much details with a biosafety stand-point):
   14. Do you keep permanent records describing the source and nature of samples:
   15. Do you know if the samples have been confirmed positive for any infectious agents that need a biocontainment level above II:
   16. Is Ethics approval obtained for this proposal/project:
   17. What will you do with the bio-specimen (explain for each type):
   18. How will you process the bio-specimen for what you intend to do (explain for each type):
   19. Does your procedure generate aerosols from the bio-specimen before treating it with denaturing agents:
   20. If YES, then you should carry out the procedure within a Biosafety hood. Will you comply/already complied? Explain:
   21. What other biosafety concerns do you foresee in carrying out this / these procedure in your bio-specimens:
   22. What are the remedial measures you envisage:
   23. Does your work involve primary or established cell lines? If YES which ones and what are the potential IAs these cells may be harbouring:
   24. What is the level of biocontainment recommended while working with these cells/IAs (described in CDC guidelines for Biosafety in Microbiological and Biomedical Laboratories 5th Edition):
   25. How will you ensure biosafety while working with these cell lines/IAs:
   26. What is the kind of waste generated from your experiments and how will they be disposed of:
5. Biosafety questions/issues arising due to research on IAs cultured/grown in the labs at SNU.
   1. What IA are you working with:
   2. What form is the starting material of the agent in (Ex. DNA, RNA, whole organism, cell line):
   3. How will you culture/grow this agent, which lab:
   4. What level of biocontainment is prescribed in the CDC guidelines to culture/grow this agent (CDC guidelines for Biosafety in Microbiological and Biomedical Laboratories 5th Edition):
   5. How will you comply with this requirement:
   6. Briefly describe what you will do with grown/cultured agent:
   7. What is the Biosafety concern(s) in this experiment(s):
   8. How will you deal with the concern(s):
   9. Is there a chance that the agent may escape to the environment:
   10. If YES, how will you deal with it:
6. Biosafety questions/issues arising due to genetically modified organisms (GMOs)/living modified organisms (LMOs).
   1. Does your proposal/project involve work with GMOs/LMOs:
   2. If YES, which ones: Lentivirus particles (3rd Generation plasmids)
   3. What will you do with the GMO/LMO (describe in some detail the experiment):
   4. What is the biosafety concern in this experiment(s): None. These are safe experimental tools. Spillage of culture media will be cleaned with excess of Bleach.
   5. How you will deal with the issue(s): Standard BSL-2 lab practice
   6. Is there a chance that the GMO/LMO will be released in the environment: No
   7. If YES then what precaution is taken/will be taken: NA
7. Biosafety questions/issues arising due to rDNA materials.
   1. Does your proposal/project involve rDNA material:
   2. If YES, describe in brief the material:
   3. What will you do with the rDNA material:
   4. What is the biosafety concern in this experiment(s):
   5. How you will deal with the issue(s):
   6. If the rDNA material is released in the environment, what is the potential biosafety concern and how you will prevent that:
8. Any specific reason why this application is made:
9. Any other comments:

# DECLARATION

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

# NAME: DESIGNATION:

**SIGNATURE OF APPLICANT WITH DATE**

# NAME OF HOD: DEPARTMENT:

**SIGNATURE OF HOD WITH STAMP AND DATE**

…………………………………………………………………………………………………..

## For Office use only:

*Application number:*

*Name of PI:*

*Title of the project:*

*Duration of the Project:*

*Date submitted to IBSC:*

*Date evaluated:*

*Comments:*

## Recommendation:

*The application submitted by, Dr/Prof……………………………………………………………. to the IBSC, for biosafety compliance of the proposal/project described below was duly evaluated by the committee in its general/special meeting held on… The committee, after*

*having gone through the biosafety concerns involving the project and remedial measures to be undertaken/already in place as explained by the applicant and as per appropriate prescribed guidelines, hereby,*

RECOMMENDS / PROVISIONALLY RECOMMENDS / NOT-RECOMMENDS (circle appropriate

one) This *proposal/project is for execution at SNU.*

*Further, the RECOMMENDATION is bound by the terms and conditions specified in the HANDBOOK for INSTITUTIONAL BIOSAFETY COMMITTEES (IBSCs), Third Revised Edition September 2020.*

*Chair, IBSC (Signature and Date with Seal)*