FORM C1

APPLICATION TO IBSC / INFORMATION TO RCGM TO CARRY OUT RESEARCH AND DEVELOPMENT INVOLVING HAZARDOUS MICROORGANISMS (HMOs), GENETICALLY MODIFIED ORGANISMS (GMOs)/ LIVING MODIFIED ORGANISMS (LMOs) FOR HEALTH CARE AND INDUSTRIAL USE

Project No:
Submission date:
(*to be filled by IBSC secretariat*)

1. Name of the Applicant:

   Designation:

   Address *(Please include mobile no & email ID)*

2. Title of the Project:

3. Status of the Project: Ongoing / New

4. Proposed work objective(s):
   (furnish details of key objectives and scientific background of the project as bullet points)

5. Proposed work plan

   5.1. Summary of the proposed work plan utilizing HMOs, GMOs/LMOs and product(s) thereof:
   (Indicate laboratory studies proposed to be undertaken including basic transformation, expression of target gene(s), Standardization of fermentation/ production procedure(s), etc., as bullet points)

   5.2. Category(ies) [Biosafety level(s)] of experiments to be performed

   5.3. Level of containment and facilities appropriate for the proposed work:

   5.4. Location(s) at which research work would be performed and details of contact person(s)

   5.5. Level of containment and facilities existing at above location(s):

6. Description of the HMOs, GMOs/LMOs and product(s) thereof proposed to be employed in the research proposal (in scientific terms)

   6.1. Taxonomy of host(s) or the host(s) carrying the vector(s)/target gene(s):

   6.2. Morphology & Physiology

   6.3. Belonging to Risk Group(s)/ Risk Category(ies) before genetic modification, if any:

   6.4. Belonging to Risk Group(s)/ Risk Category(ies) after genetic modification, if any:

   6.5. History of use:
   (Provide the details on its environmental stability; toxicity; allergenicity; virulence/ pathogenicity; host range; transmissibility and treatment options)

   6.6. Anticipated new characters in GMOs/LMOs and product(s) thereof and expected difference as compared to conventional counterparts:

   6.7. Anticipated functions of the product(s)

   6.8. Proposed fate of the HMOs, GMOs/LMOs and product(s) thereof:

7. Details on

   7.1. Source of nucleic acid(s)

   7.2. Description of the target gene(s) and mode of action, if known:
   (Provide details of target gene(s) that will be inserted, deleted or modified, and associated genetic elements e.g. promoter/ enhancer elements, introns, polyadenylation sequences)

7.3. Vector map and Nucleic acid/ amino acid sequence(s) of the gene(s) incorporated/ to be incorporated into the host organism:
(Provide nucleic acid/ amino acid sequence of the target gene(s) in FASTA format with accession number. If any)

7.4. Description of the other gene(s) (such as marker, reporter gene, etc) inserted, deleted or modified, if any:

7.5. Details of gene construct, if any:
(Provide annotated restriction maps of the gene construct(s) defining start & end positions of each genetic element along with salient features of key gene(s)

7.6. Number of copies of the genes incorporated:

7.7. Whether the product(s)of target gene(s) have been implicated in toxic and/or allergenic effect: Yes / No

8. Anticipated exchange of HMOs, GMOs/LMOs and product(s) thereof for research purpose, if any:
(Provide details of probable material(s) to be exchanged along with details of exchangers)

9. What precautions will be taken to prevent any unintended dispersal of the HMOs, GMOs/LMOs and product(s) thereof?

10. Proposed decontamination and disposal mechanisms

11. Contingency plan and risk management measures in case of an unintentional release of the HMOs, GMOs/LMOs and product(s) there of:

12. Appropriate references and any other relevant information

13. Confidential information?

14. Whether the HMOs, GMOs/LMOs and product(s) thereof under consideration, have been deliberated earlier by the RCGM? If so, provide relevant

15. Declaration by The Applicant:

- I declare that I am familiar with, and agree to comply with all the provisions mentioned in the regulations and Guidelines on Biosafety of recombinant DNA Research and Biocontainment,2017 and Guidelines & Handbook for Institutional Biosafety Committee(IBSC),2011 and other applicable Guidelines, as modified time to time by the Goverment of India.
- I would ensure that all investigators/ researchers and staff working in the area of HMOs, recombinant DNA, GMOs/LMOs and product(s) thereof understand and follow the aforesaid biosafety guidelines.
- I assure that adequate training would be conducted to create awareness about compliance requirements while working with biorisk inherent microorganisms and/ or recombinant organisms.
- The HMOs, GMOs/LMOs and product (s) thereof (transferred material), if any, will be utilized for RCGM approved purpose(s) only.
- I also assure that deviations to the above provisions, if any; arising out of the experiments would be brought to the notice of the Chairman-IBSC and the Member Secretary-RCGM immediately.
- I am aware that making false or misleading statements may attract penalty under the Environment (Protection) Act, 1986

Name: Signature with Stamp & date
Designation:

16. Certified / Forwarded by the Chairman & DBT Nominee of the IBSC

- I certify that the information contained in this form has been checked by the Institutional Biosafety Committee (IBSC) and found to be complete.
- I further certify that investigator(s), researcher(s) and staff intended to work with HMOs, recombinant DNA, GMOs/LMOs and product (s) thereof have adequate training and experience for the proposed dealings.
- The proposal set out above has been considered and approved by the IBSC in its meeting held on _____ as the agenda item no. _____ and is approved / forwarded to RCGM for further necessary action

Name: Dr Geetanjali Sachdeva Signature with Stamp & date
Designation: Chairman

Name: Dr Sanjay Biswas Signature with date
Designation: DBT Nominee