Form B3 APPLICATION TO RCGM FOR EXPORT OF HAZARDOUS MICROORGANISMS (HMOs), GENETICALLY MODIFIED ORGANISMS (GMOs)/LIVING MODIFIED ORGANISMS (LMOs) AND PRODUCT(S) THEREOF FOR RESEARCH AND DEVELOPMENT PURPOSE

1. Applicant Details :

Instructions to follow

Name of Applicant : First Name Last Name

Designation :

Address/Line-1 :

Address/Line-2 :

State / UT :

District :

Village / Town / City :

Pin Code :

Office Phone Number :

With STD Code.

Mobile No :

Email :

2. Application for :

Furnish details of material(s) to be exported, along with name of the organizations/ entities exchanging the material.

3. Product Code :

Choose/ generate the CODE, which explicitly conveys the essence of the proposed work. Kindly note that the same code might be used for generation of future references.

4. Proposed work objective(s) :

Furnish details of key objectives and scientific background of the projects as bullet points.

5. Summary of the proposed work plan utilizing HMOs, GMOs/LMOs and product(s) thereof :

Indicate studies proposed to be undertaken, as bullet points.

6. Description of the HMOs, GMOs/LMOs and product(s) thereof (in scientific terms) :

6.1: Taxonomy (common and scientific) and geographical origin of host(s) or the host(s) carrying the vector(s)/ target gene(s) :

6.2: Morphology & Physiology :

6.3: History of use :

Provide the details on its environmental stability; toxicity; allergenicity; virulence/ pathogenicity; host range; transmissibility and treatment options.
If the provided space is insufficient to furnish complete details, please enclose the relevant information.

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

Regulation & Guidelines for Recombinant DNA Research & Biocontainment 2017.

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

Regulation & Guidelines for Recombinant DNA Research & Biocontainment 2017.

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

7. Details on :

If the provided space is insufficient to furnish complete details, please enclose the relevant information as annexure

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: 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.

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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 gene 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?

If yes, please include relevant details.

○ YES ◉ NO

7.8: Manipulative procedures to be used :

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8. Proposed Quantity to be exported:

8.1:Quantity of HMOs, GMOs/LMOs and product(s) thereof to be exported:

. Please specify the number and type of total packs such as vials, tubes, plates, bottle, paper, etc., and the material, number, size and quantity in each pack.
. Please enclose a copy of the Material Transfer Agreement duly signed by both parties specifying the details (including quantity) of material being transferred.

	S. No.	HMOs, GMOs/LMOs and product(s) thereof to be exported	Quantity	Type of pack	Size	Concentration
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8.2: Justify the proposed quantity of export:

9. Details of earlier exports & imports:

9.1: Whether the proposed HMOs, GMOs/LMOs and product(s) thereof was exported earlier?

If yes, enclose the copy of relevant permit issued previously and quantities exported (Please specify the number and type of total packs such as vials, tubes, plates, bottles, papers, etc., and the material, number, size and quantity in each pack as the case may be).

○ Yes ◉ No

9.2: Whether the proposed HMOs, GMOs/ LMOs and product(s) thereof was imported earlier?

If yes, provide the copy of relevant permit(s) issued previously and duly signed/ stamped challan receipt(s) by the receiver along with details of quantities received by the receiver.

○ Yes ◉ No

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10. Recipient and transport details:

10.1: Details of recipient where HMOs, GMOs/LMOs and Product(s) proposed to be exported:

Name of Contact Person : First Name Last Name

Name of the Organization / Agency :

Please give complete Organization Name, avoid abbreviations.

Address/Line-1 :

Address/Line-2 :

Country :

State / Province :

Village / Town / City :

Pin Code/ Zip Code :

Telephone No. :

With STD Code.

Email :

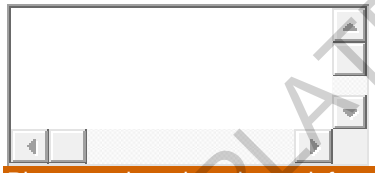
10.2 Mode of Transport :

Rail Road Air Ship

11. Safety norms & containment measures to be observed during transit :

12. Proposed decontamination, disposal mechanisms & risk management measures :

13. Appropriate references and any other relevant information :



Please enclose the relevant information as annexure

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14. Confidential information?

Would you like to designate any of the information furnished above as a confidential? If yes, provide details thereof as bullet points along with justification.

Yes No

15. Whether the HMOs, GMOs/LMOs and product(s) thereof under consideration, have been deliberated earlier by the RCGM? If so, provide relevant 'Unique Application Code (UAC)' assigned for each of those deliberations :

	S.No.	Unique Application Code (UAC)
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16. 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 for 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 also undertake that provisions of the Biological Diversity Act,2002 are complied with.
- I am aware that making false or misleading statements may attract penalty under the Environment (Protection) Act, 1986.

Name :

Designation : **Signature with stamp & Date:**

• To be signed in original by hand. (Electronic/ scanned signatures not acceptable)

17. Certified & Forwarded by the Chairman of the IBSC:

Submission of Minutes of the IBSC meeting is obligatory. Kindly note that minutes older than two years are void. Please refer FAQs for submission of minutes of the IBSC meeting.

- 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 forwarded to RCGM for further necessary action (Copy of the duly signed minutes of relevant meeting is enclosed).

Please enclose duly signed minutes of the IBSC meeting in which the proposal under consideration was deliberated and approved by the IBSC

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Name :

Designation : Chairman **Signature with stamp & Date:**

• To be signed in original by hand. (Electronic/ scanned signatures not acceptable)