

Form C1 INFORMATION TO RCGM TO CARRY OUT RESEARCH AND DEVELOPMENT INVOLVING HAZARDOUS MICROORGANISMS (HMOs), GENETICALLY MODIFIED ORGANISMS (GMOs)/ LIVING MODIFIED ORGANISMS (LMOs) FOR HEALTHCARE AND INDUSTRIAL USE

1. Applicant Details :

Instructions to follow

Name of Applicant :	<table><tr><td>First Name</td><td>Last Name</td></tr><tr><td><input type="text"/></td><td><input type="text"/></td></tr></table>	First Name	Last Name	<input type="text"/>	<input type="text"/>
First Name	Last Name				
<input type="text"/>	<input type="text"/>				
Designation :	<input type="text"/>				
Address/Line-1 :	<input type="text"/>				
Address/Line-2 :	<input type="text"/>				
State / UT :	<input type="text"/>				
District :	<input type="text"/>				
Village / Town / City :	<input type="text"/>				
Pin Code :	<input type="text"/>				
Office Phone Number :	<input type="text"/>				

With STD Code

Mobile No :	<input type="text"/>
Email :	<input type="text"/>

2. Application for :

<input type="text"/>

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.

<input type="text"/>

4. Status of the Project :

<input type="radio"/> Ongoing	<input checked="" type="radio"/> New
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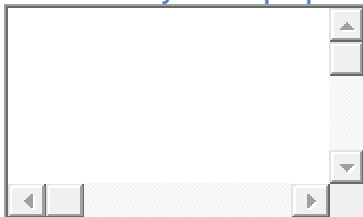
5. Proposed work objective(s) :

<input type="text"/>

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

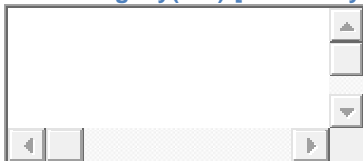
6. Proposed work plan :

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



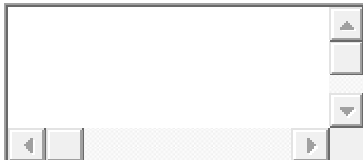
Indicate laboratory studies proposed to be undertaken including basic transformation, expression of target gene(s), Standardization of fermentation/ production procedure(s), etc., as bullet points

6.2: Category(ies) [Biosafety level(s)] of experiments to be performed :

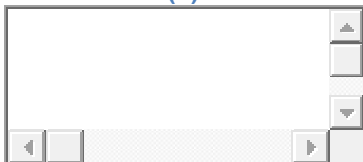


As per DNA Safety Guidelines, 1990

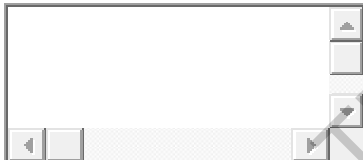
6.3: Level of containment and facilities appropriate for the proposed work :



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



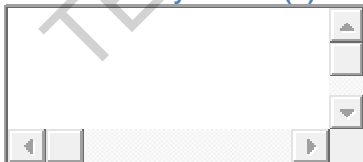
6.5: Level of containment and facilities existing at above location(s) :



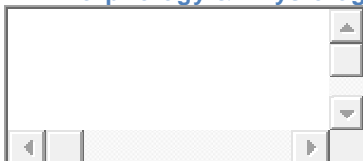
7. Description of the HMOs, GMOs/LMOs and product(s) thereof proposed to be employed in the research proposal (in scientific terms) :

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

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



7.2: Morphology & Physiology :



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

As per DNA Safety Guidelines, 1990

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

As per DNA Safety Guidelines, 1990

7.5: 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 as annexure

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

7.7: Anticipated functions of the product(s) :

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

8. Details on :

8.1: Source of nucleic acid(s) :

8.2: 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

8.3: 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

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

8.5: 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)

8.6: Number of copies of the genes incorporated :

8.7: Whether the product(s) of target gene(s) have been implicated in toxic and/or allergenic effect?

☐ YES

☒ NO

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9. 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

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

11. Proposed decontamination and disposal mechanisms

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

Please enclose the relevant information as annexure

13. Appropriate references and any other relevant information :

Please also provide details of citations included in the application, if any

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14. Confidential information?

☐

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)
<input type="checkbox"/>	01	<input type="text"/>

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 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 Government 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 :

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)