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| Institute emblem | Sree Chitra Tirunal Institute of Medical Science and TechnologyThiruvananthapuram, Kerala |

#### INSTITUTIONAL BIOSAFETY COMMITTEE (IBSC)

APPLICATION FOR BIOSAFETY REVIEW

**Notification of intention of use or manipulation/import/export/and storage of genetically modified microorganisms or cells or transgenic organisms**

**Section I: ADMINISTRATIVE**

### Application No. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Date of Receipt**: (dd) (mm) (yy)

**Title of Project/ Work:**

1. **INVESTIGATORS:**

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| **1. Principal Investigator:** |
| Name: Designation:  Email ID: |
| **1.1 Co- Investigator(s)** |
| **(1)** Name: Designation:  Email ID: |
| **(2)** Name: Designation:  Email ID: |
| **(3)** Name: Designation:    Email ID: |
| **1.3 Send Correspondence to: [ ] PI; [ ] PI & Co-I No. ( ); [ ] Only to Co-I No. ( )** |

**(B) DURATION OF PROPOSED STUDY:**

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| **2. Month and year of likely commencement of the study:** |
| **2.1 Duration of the study:** |

1. **FUNDING:**

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| **3. Type of funding:** |
| **3.1 Status of funding:**  [ ] Funding awarded/available [ ] Fund application pending |

**(C) Project Summary**

**(D) Project Details :**

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| **4. Purpose:** |
| **4.1 New / Ongoing:** |
| **4.1.1 If ongoing: Briefly state whether applied to IBSC earlier and purpose for which permission granted:** |
| **5. Genetic manipulation details: Does the project involve genetic manipulation/rDNA work : Yes / NO** |
| **5.1 Description of target genes and gene product:** |
| **5.3 Source of nucleic acid :**  **5.3.1 Character it codes for:**  **5.3.2 Specification of nucleic acid sequence:** |
| **6. Vector Host system to be used:(please enclose map of Vector/ gene)**    **6.1 Manipulative procedures :** |
| **7. Subsequent use or distribution of DNA:** |
| **8. Whether the transgenic/transformed organism will be used for overexpression and purification of rDNA products:**  **If yes**  **8.1 Basic transformation and laboratory work to assess the expression of target gene:**  **\*8.2 Standardisation of fermentation procedures below 20 Litres (if applicable)** |
| 1. **Physico- Chemical charectisation of product:**   **9.1 Assessment of toxicity and allergenicity of product ( if applicable provide details of experimentation )** |
| **E. SITE** |
| **10. Working environment (containment strategy to be adopted/ proposed):**  **10.1 Containment facility available with the investigators with location:** |
| **11. List of staff involved with the proposal** |
| **12. Does your study involve use of transgenic animals /plants either purchased or self developed** |
| **If yes,** |
| **12.1 Details** |
| **12.2. Source:**  **12.2.1 Risk Status:**  **12.2.2. Containment facility needed:** |
| **13. Containment facility present with the investigator:** |
| **14. Details of disposal of waste generated commensurate with risk :** |

**F. Declaration**

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| 15. The information provided in this form is to the best of my knowledge accurate. I have ensured that all persons nominated in the initial submission or their successors are fully aware of and are in agreement with the proposal  Signed Proposer Date |
| 16. I agree to act as Biological Safety Officer in connection with the proposed work in this submission  Signed Biological safety Officer Date |

**G. For Use of IBSC**

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| **17. The proposal set out in this submission has been considered by The Institutional Biosafety Committee and the comments of the committee are as follows:**  Signed Chairman IBSC Date |

**Excerpts from Government of India guidelines**. This is for information. In case of any doubt please contact Secretary, IBSC (Email ID: [anmaya@sctimst.ac.in](mailto:anmaya@sctimst.ac.in)):

**5. Classification of microorganisms or genetically engineered product**  
(1) For the purpose of these rules, microorganisms or genetically engineered organisms, products or cells shall be dealt with under two major heads; animal, pathogens and plant pests and these shall be classified in the manner specified in the Schedule.   
  
(2) If any of the microorganisms, genetically engineered organism or cell falls within the limits of more than one risk class as specified in the Schedule, it shall be deemed to belong exclusively to the last in number of such classes.   
  
**6. Microorganisms laid down in the Schedule are divided into the following:-**  
(i) Bacterial Agents;  
(ii) Fungal Agents;  
(iii) Parasitic Agents;  
(iv) Viral, Rickettsial and Chlamydial Agents;  
(v) Special Category.  
  
**7. Approval and Prohibitions etc.**  
(1) No person shall import, export, transport, manufacture, process, use or sell any hazardous microorganisms of genetically engineered organisms/substances or cells except with the approval of the Genetic Engineering Approval Committee.   
  
(2) **Use of pathogenic microorgnisms or any genetically engineered organisms or cells for the purpose of research shall only be allowed in laboratories or inside laboratory area notified by the Ministry of Environment and Forests for this purpose under the Environment (Protection) Act, 1986.**  
(3) The Genetic Engineering Approval Committee-shall give directions to the occupier to determine or take measures concerning the discharge of microorganisms/genetically engineered organisms or cells mentioned in the Schedule from the laboratories, hospitals and other areas including prohibition of such discharges and laying down measures to be taken to prevent such discharges.   
  
(4) Any person operating or using genetically engineered organisms/microogranisms mentioned in the schedule for scale up or pilot operations shall have to obtain licence issued by the Genetic Engineering Approval Committee for any such activity. The possessor shall have to apply for license in prescribed proforma.   
  
(5) Certain experiments for the purpose of education within the field of gene technology or microorganism may be carried out outside the laboratories and laboratory areas mentioned in sub-rule (2) and will be looked after by the Institutional Biosafety Committee.

**8. Production**  
Production in which genetically engineered organisms or cells or micro- organisms are generated or used shall not be commenced except with the consent of Genetic Engineering Approval Committee with respect of discharge of genetically engineered organisms or cells into the environment. This shall also apply to production taking place in connection with development, testing and experiments where such production, etc., is not subject to rule 7.   
  
**9. Deliberate or unintentional release**  
(1) Deliberate or unintentional release of genetically engineered organisms/hazardous microorganisms or cells, including deliberate release for the purpose of experiment shall not be allowed.   
Note: Deliberate release shall mean any intentional transfer of genetically engineered organisms/hazardous, microorganisms or cells to the environment or nature, irrespective of the way in which it is done.   
  
(2) The Genetic Engineering Approval Committee may in special cases give approval of deliberate release.

**10. Permission and approval for certain substances**  
Substances and products, which contain genetically engineered organisms or cells or microorganisms shall not be produced, sold, imported or used except with the approval of Genetic Engineering Approval Committee.   
  
**11. Permission and approval for food stuffs**  
Food stuffs, ingredients in food stuffs and additives including processing and containing or consisting of genetically engineered organisms or cells, shall not be produced, sold, imported or used except with thc approval of the Genetic Engineering Approval Committee.

**12. Guidelines**  
(1) Any person who applies for approval under rules 8-11 shall, as determined by the Genetic Engineering Approval Committee submit information and make examinations or cause examinations to be made to eradicate the case, including examinations according to specific directions and at specific laboratories. He shall also make available an on-site emergency plan to GEAC before obtaining the approval. If the authority makes examination itself, it may order the applicant to delay the expenses incurred by it in so doing.   
  
(2) Any person to whom an approval has been granted under rules 8-11 above shall notify the Genetic Engineering Approval Committee of any change in or addition to the information already submitted

**13. Grant of approval**   
  
(1) In connection with the granting of approval under rules 8 to ll above, terms and conditions shall be stipulated, including terms and conditions as to the control to be exercised by the applicant, supervision, restriction on use, the layout of the enterprise and as to the submission of information to the State Biotechnology Co-ordination Committee or to the District Level Committee.   
  
(2) All approvals of the Genetic Engineering Approval Committee shall be for a specific period not exceeding four year at the first instance renewable for 2 years at a time. The Genetic Engineering Approval Committee shall have powers to revoke such approval in the following situations:-

(a) If there is any new information as to the harmful effects of the genetically engineered organisms or cells.   
  
(b) If the genetically engineered organisms or cells cause such damage to the environment, nature or health as could not be envisaged when the approval was given, or   
  
(c) Non compliance of any condition stipulated by Genetic Engineering Approval Committee.