Form 1

Proforma for submitting application to IBSC/RCGM to carry out research and development work on GMOs/LMOs/r-DNA products/pharmaceuticals

1. Name of the Applicant
   Designation
   (a) Address (Registered Office)

   Telephone No.
   Telex No.
   Fax No.
   E-mail

   (b) Address (Research Station)

   Telephone No.
   Telex No.
   Fax No.
   E-mail

2. Basic information on application:

   2.1 Purpose
   2.2 New Yes No
   2.3 Ongoing Project Yes No
   If yes, No. & Date(s) of previous Permit(s) issued :
   2.4 If yes, briefly state the purpose for which permission(s) granted.
   2.5 Duration: From……To……..
   2.6 Category of experiments as per the Guidelines of DBT

3. Objectives of the proposal

4. Description of the GMOs employed in the research proposal (in scientific terms; for new application only)

   4.1 Description of GMOs
   4.2 Description of the target gene(s)
   4.3 4.3 Number of copies of the genes incorporated
   4.4 4.4 Description of the target gene product(s)

5. Details on:

   5.1 Source of nucleic acid(s):
   5.2 5.2 Nucleic acid sequence (Please enclose the nucleic acid sequence map of the target gene):
   5.3 5.3 Vector(s) (Please enclose the map of the vector gene):
   5.4 5.4 Host(s) that carrying the vector(s)/ target gene(s):
   5.5 5.5 Manipulative procedures:
   5.6 Anticipated functions of Product(s)

6. Summary of the proposed work plan utilizing GMOs (please check it from the following areas and provide the details of work plan).

   6.1 Basic transformation and laboratory work to assess the expression of the target gene
   6.2 6.2 Standardization of fermentation procedures below 20 lt. capacity (if applicable)

7. Assessment of toxicity and allergenicity of the product (if yes, please provide the

following information)

i) Production / fermentation procedures adopted
ii) Purification procedures adopted; state briefly the processing chemicals used in the purification steps.
iii) Physico-chemical characterization of the product; please provide limits of residues with there characterization/ identification.
iv) Biochemical/immunological characterization of the product
v) Information on Five batches production data
vi) Toxicity and Allergenicity protocols and the address of the lab/ Institute where these studies are proposed to be conducted.
vii) Institutional Animal Ethics Committee's Approval.
viii) Acceptability criteria of the bulk and the formulated material wherever ready for animal experiments.

8. Site/ Location of the research work:

9. Proposed containment facility (Please indicate the level of containment proposed and attach IBSC inspection report):

10. Standard operating procedures (SOPs) for decontamination and disposal mechanisms

11. Risk management measures practiced (Emergency plan)

12. Any other relevant information

13. Declaration:

I declare that the information provided in the above format is correct and accurate to the best of my knowledge. The "Safety Guidelines" brought out by the Department of Biotechnology, Ministry of Science & Technology, Govt. of India will be and is being strictly followed. In case any untoward incident occurs, the Chairman of the IBSC and the Member-Secretary of the RCGM will be informed immediately.

Place:

Date: Signature of the Applicant

14. Recommendations:

The proposal set out above has been considered by the "Institutional Biosafety Committee" in its meeting held on _____ and is forwarded to RCGM for further necessary action.

Place:

Date: Signature of the Chairperson, IBSC

(Note: Please submit 20 copies of the application to the Department of Biotechnology for placing the same in the meeting of RCGM)

Form II

INSTITUTIONAL BIOSAFETY COMMITTEE -- SUMMARY SHEET

(TO BE FILLED BY PRINCIPAL INVESTIGATOR)

Please tick and answer yes/no. All aspects to be filled completely

1) Project Title:

2) Name of PI:

3) Name of participant:

4) Brief description of the study (~ 200 words):

5) Methodology involving risk agents (~ 200 words):

6) (i) Proposed Category: I: _____; II: _____; III: _____; IV_____

(ii) If category III: whether person has experience of working with category I/II agents: Yes/No. If yes, then duration: …….years……months

7) (i) Level of BSL Containment: I _____; II: _____; III: _____; IV: _____

(ii) If category III: whether person has experience of working with category I/II agents: Yes/No. If yes, then duration: …….years……months

8) Area / Discipline Plant : _____ Animal: _____
Eukaryotic _____ Prokaryotic _____
Others: _____ Specify: _____

5A) Material handled with respect to plants and animals including primates involves

Animal: Virus: _____; Bacteria: _____; Fungi: _____; Others: _____
Plant: Virus: _____; Bacteria: _____; Fungi: _____; Others: _____

5B) Material referred in 5A is (with respect to plants and animals including primates)
Whole organism: _____ Live _____ Inactive _____
Infectious: _____ Mode of Spread _____
Non infectious _____ : Isolated Protein: _____DNA _____RNA _____
: Others: _____ Specify: _____
Will the material be introduced into live plants/animals: _____

5C) Is material Toxinaceous: _____; Allergenic: _____; Pathogenic: _____.

6) Project involves a) Vaccine: _____; b) immunization: _____
c) Animals: _____; d) Plants: _____

7) Is approval from IAEC (Institutional Animal Ethics Committee) needed?
(Any special comment, if any, by Investigator may also be added here)

8) Approval comments if any (to be filled by IBSC member)

Investigator signature IBSC-MEMBER Signature

Form III

INSTITUTIONAL BIOSAFETY COMMITTEE

INVERSTIGATOR DECLARATION FORM

Project Title:

Project Summary (Five lines):

Principal Investigator:

Co-Investigator:

1) IBSC Approval Not Required since the proposal does not need it since it is not under its purview _____ (Tick if applicable)

2) Although rDNA work is involved, IBSC approval not required since the proposal involves routine rDNA work of category I and has no GMO that needs specialised biosafety precautions. _____ (Tick if applicable)

3) rDNA work is involved, IBSC approval required and has no GMO that needs specialised biosafety precautions. _____ (Tick if applicable)

4) IBSC Approval definitely required and RCGM needs to be informed. A Provisional approval is enclosed/pending _____ (Tick if applicable)

I/we are aware of the general rules concerning biosafety (Please refer to the web site at http://dbtbiosafety.nic.in for the DBT Biosafety Regulations). I will comply and follow the Biosafety guidelines. I understand that the Panjab University, Chandigarh will not be held responsible for any violation of Biosafety rules by me and my staff regarding biosafety precautions pertaining to the above project proposal.

Investigator signature IBSC-MEMBER Signature