WHO SHOULD FILL THE FORM
This page need not be submitted – only for reading

1) All projects working with recombinant DNA.
CSSP will not process without IBSC consideration

Project Categories (Mention in Item 2.5 of IBSC Form)

2) Category I: Routine rDNA projects that do not need elaboration (Item Nos 1, 2, 3, 6, 8 & 9 of ANNEX-II and Summary Sheet to be filled)

Experiments involving non-pathogenic and non-infectious viral, bacterial or fungal DNA and its manipulation, expression and cloning to answer questions that are basic in nature or those that allow indirect extrapolations to higher organisms eg *E. coli* etc. Products or experimentally derived materiel should also be non-toxic, non-pathogenic and non-infectious and pose no hazard to the environment.

3) Category II: rDNA projects that need elaboration (All items of ANNEX-II that are applicable and Summary Sheet to be filled)

Experiments needing basic containment (level II, BSL II) and involves DNA that is derived from potentially infectious or pathogenic organisms and is not potentially dangerous or infectious by itself or when cloned into vectors. Its manipulation, expression and cloning in the lab may involve laboratory animals but does not generate products that pose a hazard to the environment, animals and plant populations eg DNA vaccines etc. Large scale production of recombinant (>20 litres) products would also be treated in this category.

4) Category III: rDNA projects needing elaboration & biosafety precautions (All items of ANNEX-II and Summary Sheet to be filled)

Experiments needing containment levels III and IV (BSL III & IV. Experiments involving whole organisms that are potentially harmful, pathogenic and infectious to humans and the environment. Experiments involving organisms that have the ability to spread in humans either through the air or through vectors or other contact. Experiments involving DNA that could become pathogenic or infectious to human upon manipulation in the lab. Experiments involving toxins and allergens. Experiments involving the transfection of human cells with oncogenic DNA. Experiments involving infection studies with pathogenic plant and animal viruses. Gene transfers to whole plants and animals. Experiments involving engineered and mutant organisms that pose a threat to human and plants. Experiments involving field studies and *in vivo* diagnostics. Experiments involving antibiotic resistance genes into pathogenic organisms.

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) Proposed Category: I: _____; II: _____; III: _____(ref 'Who should Fill Form)

3) Level of BSL Containment needed: I _____; II: _____; III: _____; IV: _____

4) 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

National Institute of Technology
Durgapur
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) 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) and I understand that the National Institute of Technology, Durgapur will not be held responsible for any decisions taken by me regarding biosafety precautions pertaining to the above project proposal.

_____ _____
NAME SIGNATURE

All the proposals should attach this form duly completed and signed to enable CSP to process. Please provide a copy of this form to IBSC.

IBSC FORM (ANNEX – II)

INFORMATION TO IBSC/ RCGM TO CARRY OUT RESEARCH FOR DEVELOPMENT OF R-DNA PRODUCTS

Application for clearance by IBSC/ RCGM to carry out research involving genetic engineering activity for the development of r-DNA products.

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

   Telephone No.
   Telex No.
   Fax No.
   e-mail

   (b) Address (Research Station)
   (Same as above unless experimentation is done elsewhere)
   Telephone No.
   Telex No.
   Fax No.
   e-mail

2. Application for : (Title of Project could be stated)
   - 2.1 Purpose (Basic end purpose could be stated in one/two lines)
   - 2.2 New (Tick) Yes No
   - 2.3 Ongoing Project (Tick) Yes No
     If yes, No. & Date of LOI issued :
     No. & Date of Permit issued :
   - 2.4 If yes, briefly state the purpose for which permission was granted.
   - 2.5 Category of experiments as per the Guidelines of DBT
     (Refer to 'Who should fill the form)

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 (Vector Maps etc)
   - 4.2 Description of the target gene(s)
   - 4.3 Number of copies of the genes incorporated
   - 4.4 Description of the target product(s)

5. Details on :

5.1 Source of nucleic acid(s) :

5.2 Nucleic acid sequence (Please enclose the nucleic acid sequence map of the target gene) :

5.3 Vector(s) (Please enclose the map of the vector gene) :

5.4 Host(s) that carrying the vector(s)/ target gene(s) :

5.5 Manipulative procedures : (can include brief exptal procedure)

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 Standardization of fermentation procedures below 20 It. capacity (if applicable)

6.3 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 where these studies are proposed to be conducted.

vii) Institutional Animal Ethics Committee's Approval.

6.4 Acceptability criteria of the bulk and the formulated material wherever ready for animal experiments.

7. Site/ Location of the research work :

8. Proposed containment facility (Please indicate the level of containment proposed) :

9. Decontamination and disposal mechanisms

10. Risk management (Emergency plan)

11. Any other relevant information

12. 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.

Date: Signature of the Applicant

Forwarded:

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

Date: Signature of the Chairman, IBSC

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