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

Project Categories

1) **Category I: Routine rDNA projects that do not need elaboration:**
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.

2) Category II: rDNA projects that need elaboration

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.

3) Category III: rDNA projects needing elaboration & biosafety precautions:

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

Submission of projects for approval by the Institutional Bio-safety Committee (IBSC) at KGMU

KGMU INSTITUTIONAL BIO SAFETY COMMITTEE DECEMBER 2015

In accordance with the notification of the Ministry of Environment and Forests issued under the Environment Protection Act, it has become mandatory that all research activities carried out at Research Institutes, Universities or R&D Centres involving genetically engineered organisms or genetic material (DNA/ RNA) or infectious material/ organisms be approved by the Institutional Bio Safety Committee.

It is mandate of the Institutional Bio-safety Committee of KGMU to review all "Research projects that involve cloning and/or transformation experiments and/or expression of genes in eukaryotic or prokaryotic organisms and/or handling of infectious organisms".

All investigators at KGMU who have initiated new research project(s), or have submitted new project(s) that involve cloning and/or transformation experiments and/or expression of genes in eukaryotic or prokaryotic organisms and/or handling of infectious organisms, to National/International Agencies should submit relevant information concerning their project(s) as per the IBSC format (**proforma can be downloaded from KGMU website**), along with the respective project(s) for IBSC clearance (4 **copies of each**).

The documents are to be submitted to research cell and addressed to; Member Secretary, IBSC, KGMU, Lucknow. Please send a soft copy to ibsc@kgmcindia.edu

For timely clearance, please submit the above information to IBSC at the time of project submission to the funding agency.

For information on Biosafety related issues, visit http://dbtbiosafety.nic.in/

PROJECT INFORMATION FOR INSTITUTIONAL BIOSAFETY CLEARENCE

[Please fill up separate sheet for each project and submit 8 copies of each. Both-sided printed copy of research proposal/thesis protocol to be attached at the end of each copy. The whole bunch to be submitted with a covering letter from PI, securely tied.]

1. Title and Summary of the project (max. 1 page):

2. Information on Pl:

Name:	Designation:	Department:
Telephone:	Mobile:	Email id:

3. Categorization of Research Project (refer to Annexure 1):

4. Relevant details of the project:

1. Objective(s) of the study:
2. Key words:
3. Work plan: in flow chart form with brief description (max. 3 pages)
4. Diagrammatic representation of recombinant DNA molecules to be used and constructed

5. Proposed Containment Category: (P1/P2/P3/P4)

6. Environment Risk Assessment:

a) Unmodified organism
b) Genetically modified organism (GMO)
c) Safety control level required: (Yes/No)

Certified that appropriate Biohazard sign will be/is displayed prominently at the entry of the facility

7. In case GMO is involved: categorisation

1. Source of nucleic acid
2. Specimen of Nucleic acid sequence
3. Vector host system
4. Manipulative procedures

8. IBSC Approval for Experimental Trials required (please refer to annexure 1):

(Yes /No)

9. List of laboratory researchers/staff involved with proposal:

10. Funding Agency:

11. Grant (Approved/Applied/Other):

12. Status (Ongoing/Completed/New):

13. Expected duration of the Project and dates:

From: (DD/MM/YYYY) **To:** (DD/MM/YYYY)

14. Follow-up Measures:

1. Nature of Accident,s that can happen:
2. Remedial Measures to be adopted:

15. Risk Avoidance and Management:

1. Methods adopted for personnel protection:
    a. Plan for Vaccination and other prophylactic measures (if available for the organism(s) handled)
    b. List of medical examinations to be carried out – initially and periodic
    c. Nature of orientation training to be provided to lab personnel for handling, storage and disposal of bio-hazardous material
    d. Name, contact details and consent of the person responsible for the training with justification how the person is suitable for such responsibility

    Signature of the designated person _____

    e. Name, contact details and consent of the person responsible for maintenance, disposal and upkeep of the lab along with record keeping of instruments, culture facility and disposal involving biohazardous material throughout the project duration **(The name and contact details of this person to be displayed prominently at the entry of the lab)**

    Signature of the designated person _____

    f. Certified by PI that the financial expenses for prophylaxis/vaccination (if applicable), routine initial and periodic medical examination and treatment in case of exposure will be met by/from

    Signature of PI _____

2. Emergency Plan (in research):
3. Contingency plan (in production):

16. Decontamination & disposal mechanisms:

Details on specific disposal and decontamination methods to be used for different biohazardous material to be generated in the project:

Names of biohazardous materials and methods for decontamination (Autoclave; Disinfectants and chemicals (pl. specify); Incinerator, Water-proof & chemical resistant bench tops: Available/ Not available; Sink for hand wash in each laboratory: Available/ Not available)

Specific methods to be adopted for handling and disposal of hazardous chemical waste (Ethidium Bromide/Phenol/Toluene/Any other (pl. specify):

17. Import/Exchange of material within and outside the country
(Please fill up separate sheet for each material)

Date of approval (RCGB/IBSC/HMSC)
Specimen description
Quantity approved
Date of Import/Exchange
Status

18. Subsequent use or distribution of recombinant DNA molecule(s) / samples / DNA / RNA generated in this project

(Signature)
Date: **Principal Investigator**