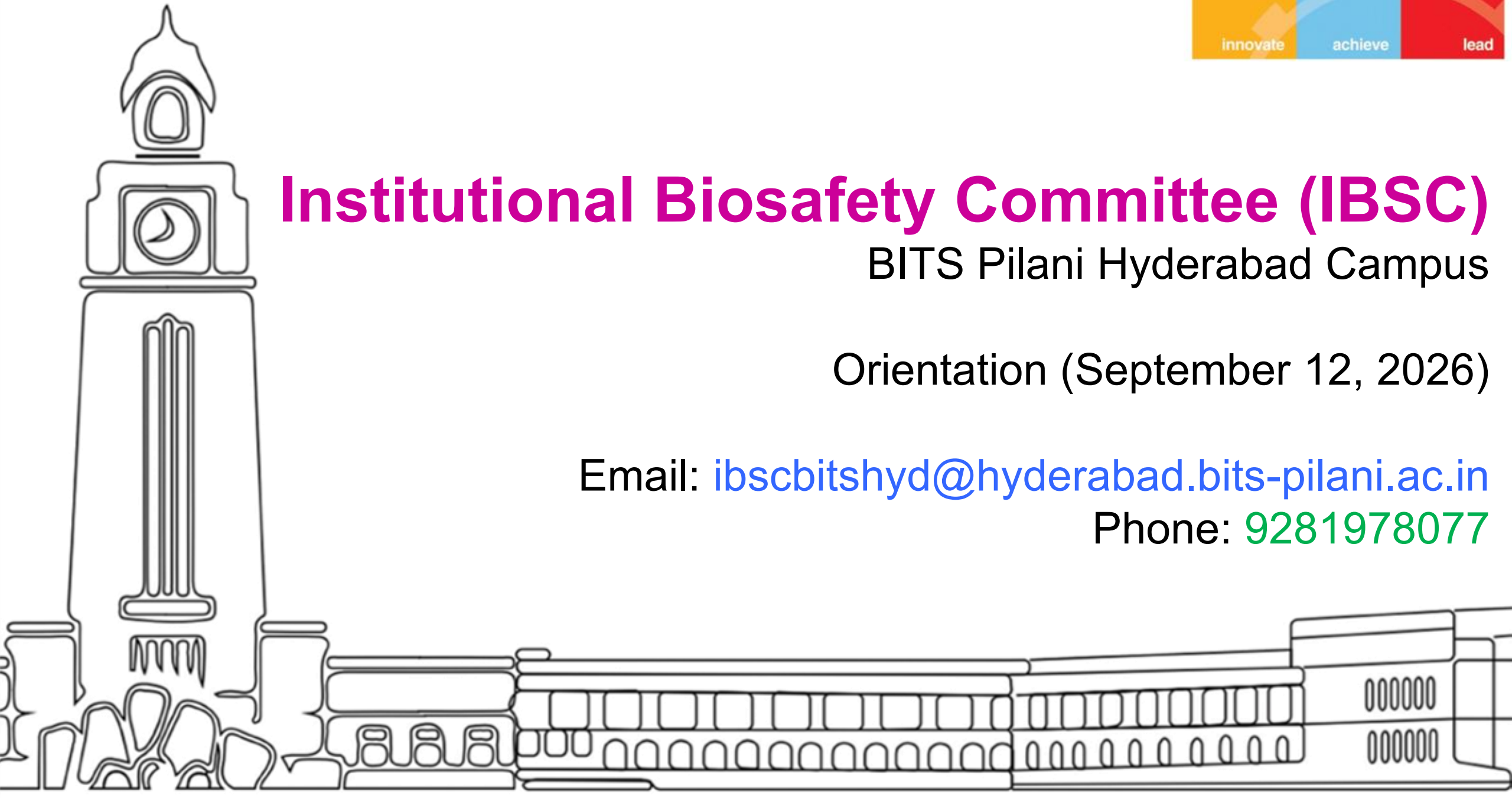


# Institutional Biosafety Committee (IBSC)

BITS Pilani Hyderabad Campus

Orientation (September 12, 2026)

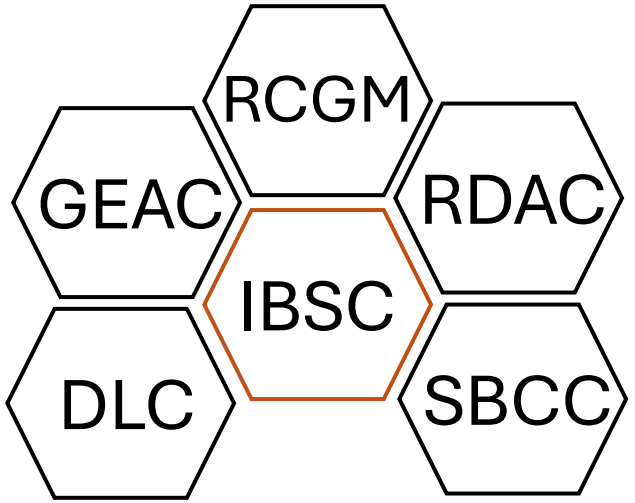
Email: ibscbitshyd@hyderabad.bits-pilani.ac.in
Phone: 9281978077

# Outline

- Introduction
- Main Activities
  - Biosafety compliance
  - Review of R&D proposals
  - Interfacing between PIs and RCGM
  - Reporting activities to RCGM

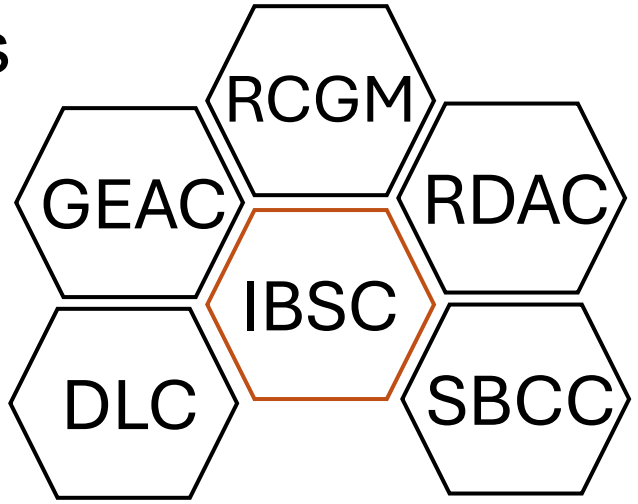
# Introduction

- Institutional Biosafety Committee
  - Part of the regulatory framework of six committees
  - Implements Biosafety measures as per the state and central government regulations
  - Coordinates and reports its activities
  - Reviews and ensures that R&D projects are conducted as per Biosafety norms
  - Enables PIs to import and export biological materials
  - Interfaces between PIs, RCGM
  - Provides approvals to PIs for obtaining grants from funding agencies



# Introduction

- Institutional Biosafety Committee
  - Reports its activities to RCGM
    - Meetings to review proposals and any incidents
    - Information on the approved projects
    - Annual compliance
    - Medical surveillance
    - Annual transaction record



# Outline

## IBSC Composition

Committee constituted by the Head of the institution and appointed by RCGM*

| Designation | Number | Name |
|---|---|---|
| Chairperson | 1 | K. Naga Mohan (Since 2017) |
| Member-Secretary | 1 | Amartya Sanyal |
| Medical Officer | 1 | Nagajyothi |
| DBT-Nominee | 1 | Abhijit Sardesai (CDFD) |
| Internal Members | ≥ 2 | Piyush Khandelia (Bio)<br>Shuvadeep Maity (Bio)<br>Abhijeet Joshi (Pharm) |
| External Members | > 1 | Raghunand Tirumalai (CCMB)<br>K.V. Rao (OU) |

* IBSC may invite other experts as needed

# Main activities

- Implements biosafety regulations in the campus
- Responds to questions raised by RCGM
- Helps PIs to answer queries from RCGM
- Reviews R&D activities in the campus and their compliance to biosafety regulations
  - Evaluation of applicants/reports related to rDNA technology work involving GE organisms and non-GE hazardous microorganisms in an organization
  - Issues IBSC-level approvals of R&D projects to the PIs
- Conducts meetings (at leased two as mandated) to review its activities
- Reports its activities (incidents and/or release) to RCGM
- Coordinates with the Head of the institution to address related issues

# Main activities

Assessment of R&D projects

- Assess and monitor items of general consideration (risk assessment, risk management, emergency plans, etc.)
  - Provide advice to PIs on the issues related to Biosafety while using GMOs/HMOs/LMOs and GE research
  - Inform PI about IBSC review, approval or rejection of applications
  - Submit/update copies of site emergency plan to RCGM, GEAC, SBCC or DLC
  - Inspect laboratories using checklists, apprise shortcoming measures (if necessary) under the information of the head of the organization and maintain inspection reports

# Main activities

| Implement | Evaluate/ consider/ review | Report | Approve |
|---|---|---|---|
| • Biosafety guidelines<br>• On site emergency plans<br>• Biosafety Training<br>• Health surveillance | • Application/ Activities*<br>• Physical safety and security measures<br>• Applications/ activities for approval | • Compliance to Rules 1989<br>• Biosafety/ biosecurity threats and management | • Category I/ II Genetic engineering<br>• Import, export, transfer, receive as per Simplified guidelines |

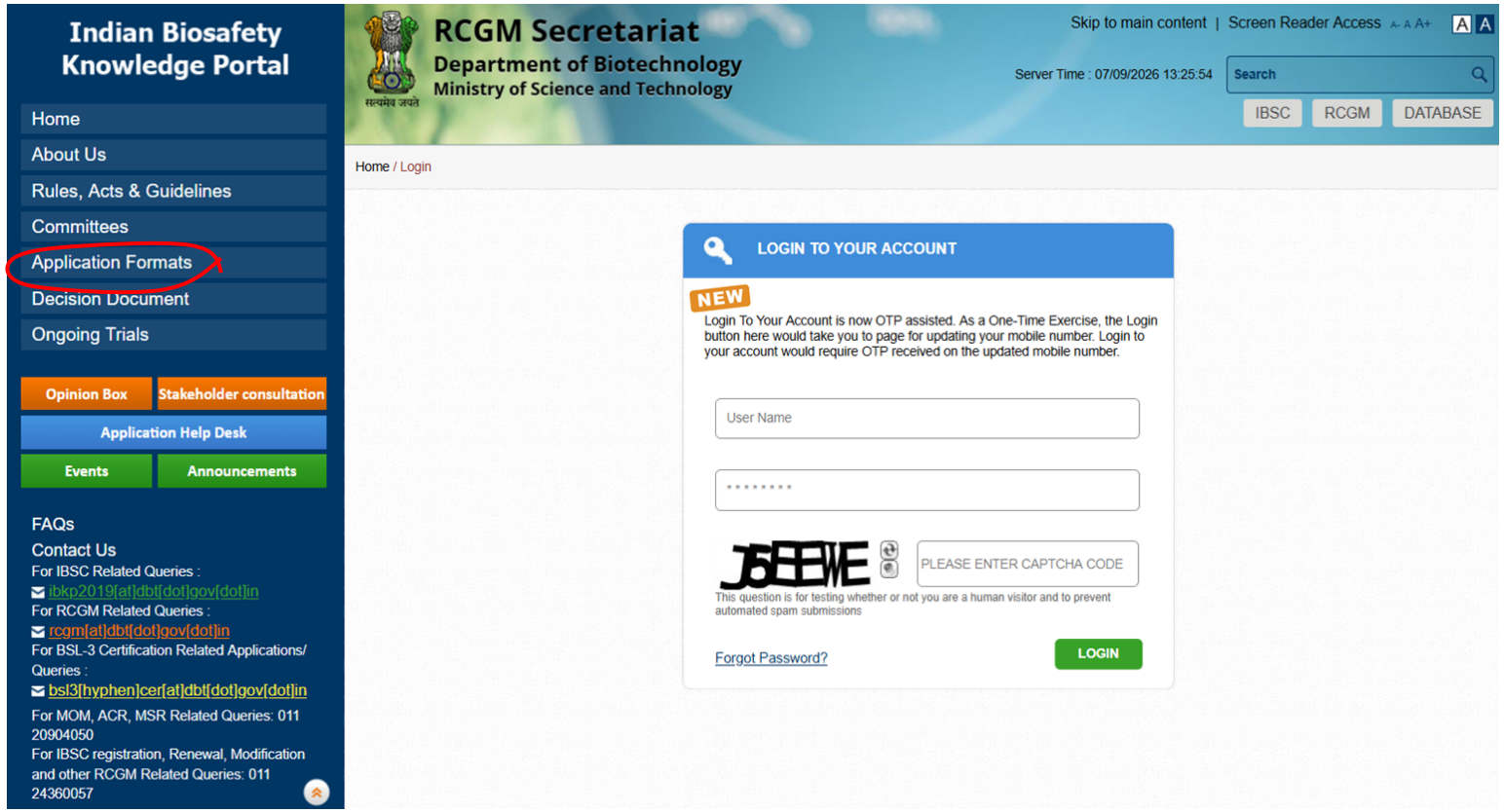
* Activities include import, export, transfer, receive, contained (laboratory) and confined R&D involving GE organisms and/or hazardous microorganisms.

# IBSC Meetings and Records

- IBSC Meets as needed, at least twice in a calendar year (usually March/April and September/October)
- Emergency Meetings: Urgent issues such as non-compliance/ unexpected events
- Minutes: Generated from the IBKP portal after deciding on which proposals were approved
- IBSC Records: Signed minutes, Annual report, Copies of applications approved, Applications forwarded
- Training of IBSC members: BSL3 & above (Not applicable)
- Training of Laboratory personnel: BSL3 & above (Not applicable), a session may be organized at the institutional level for handling GMOs/HMOs/LMOs, GE materials, etc.

# Submission of applications

- Identify the correct application(s) to submit
  - Go to https://ibkp.dbt.gov.in/Login/Login
  - Click “Application Formats” in the left panel






IBSC BITS Pilani Hyderabad Campus

# Submission of applications

- Choose the correct form(s)

TO IMPORT, EXPORT, TRANSFER AND RECEIVING OF REGULATED MATERIAL

**FORM B1:** APPLICATION TO RCGM FOR IMPORT OF HMOs, GMOs/LMOs AND PRODUCT(S) THEREOF FOR RESEARCH & DEVELOPMENT PURPOSE

FORM B1 Template for reference purpose only

**FORM B3:** APPLICATION TO RCGM FOR EXPORT OF HMOs, GMOs/LMOs &PRODUCT(S) THEREOF FOR RESEARCH & DEVELOPMENT PURPOSE

FORM B3 Template for reference purpose only

**FORM B5:** APPLICATION TO RCGM FOR RECEIVING HMOs,GMOs/LMOs & PRODUCT(S) THEREOF FOR RESEARCH & DEVELOPMENT PURPOSE WITHIN INDIA

FORM B5 Template for reference purpose only

**FORM B7:** APPLICATION TO RCGM FOR TRANSFER OF HAZARDOUS MICROORGANISMS (HMOs), GENETICALLY MODIFIED ORGANISMS (GMOs)/LIVING MODIFIED ORGANISMS (LMOs) AND PRODUCT(S) THEREOF FOR RESEARCH AND DEVELOPMENT PURPOSE WITHIN INDIA

FORM B7 Template for reference purpose only

TO CARRY OUT RESEARCH AND DEVELOPMENT

**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

FORM C1 Template for reference purpose only

TO CARRY OUT RESEARCH AND DEVELOPMENT

# Submission of applications

**Information needed**

- All points in the application must be filled
- Character limits need to be strictly followed
- If 'Not Applicable' is to be entered, this statement needs to be justified
- If materials are already existing in the laboratory, an explanation has to be provided how they were obtained
    - E.g. The HEK293T cell lines proposed to be used in this project were already obtained using an approval from IBSC under a previous project (Approved in meeting dated 18-04-2015)
    - All cell lines, microbial strains, etc. are to be used only after obtaining an appropriate permit.

# Submission of applications

**Information needed**

- In some cases, applications need approvals from IEAC and/or IHEC

  Examples:

  A recombinant DNA experiment using human or rodent DNA

  A cell line generated from human/ animal source

- Biosafety regulations see IBSC as final approval and therefore prior approvals from the above committees is required

# Submission of applications

**Information needed**

- Example forms are uploaded on IBSC website and may be used as a guideline
- The PI is solely the responsible person for the accuracy and the necessary information provided
- If additional space is required to give details, they can be given as an addendum
- Applications with missing and inadequate information need to be revised and approved only in the next possible meeting
- If another form is missing along with the main application, the application will be rejected (e.g. Form C1 submitted without Form B1/B5)

# Submission of applications

## Approval process

| | Principal Investigator | | IBSC |
|---|---|---|---|
| 1 | Obtain BioRRAP ID with the help of IBSC | ⟺ | IBSC approves the Biorrap ID |
| 2 | Obtain IBKP credentials with the help of IBSC | ⟺ | IBSC creates login credentials for the PI |
| 3 | Identify the correct forms to be filed* | | Consult IBSC website for the forms** |
| 4 | Submit the completed forms to IBSC**** | ⟺ | Refer to the filled example of online application*** |

| | |
|---|---|
| * | **It is the complete responsibility of the PI to identify the correct forms as per the guidelines of IBKP** |
| ** | The example forms are only indicators, the correct information that needs to be provided varies according to the project proposed and must be decided by the PI |
| *** | Form formats may be different from the IBKP website and the PDFs. IBSC is making its best efforts to match with the online format. If any discrepancies found, please inform IBSC |
| **** | Forms can be submitted anytime but must be within two weeks from a scheduled meeting |

# Submission of applications

## Approval process

| | Principal Investigator | | IBSC |
|---|---|---|---|
| 6 | | | IBSC Conducts meetings as needed* |
| | | | ⇩ |
| 3 | Submit revisions within stipulated time** | ⇔ | IBSC informs the outcome (approve, approve with minor modifications, reject)** |
| | ⇩ | | |
| 4 | Ensure that the approved applications are signed by the Chairman IBSC | | |
| | ⇩ | | |
| 5 | Submit the signed applications to IBKP | | |
| | ⇩ | | |
| 6 | Inform IBSC of any queries/ communications | ⇔ | IBSC can assist of formulating answers but can't take responsibilities on concealed or incorrect information |
| | ⇩ | | |
| 7 | Send IBKP the acceptance of applications | | |

| | |
|---|---|
| * | **As needed including mandatory meetings (Usually around April and October, every year)** |
| ** | IBSC can't take responsibility for incomplete and incorrect applications and can only share information on conclusions by the committee |

# Submission of applications

## BSL1 category

| S.No. | GE experiments on | | | Approvals |
|---|---|---|---|---|
| | **Microorganism** | **Animals** | **Plants** | |
| Category 1 | Insertions of gene into RG 1 microorganism having no adverse health, phenotypic or genotypic consequence.<br>Experiments involving approved host/vector systems provided that the donor DNA is originated from RG1 microorganism.<br>Self-cloning, fusion of protoplasts between nonpathogenic RG 1 organism, etc. | Breeding, housing and experiments of gene 'knockout'.<br>Breeding of GE animals Transformed with sequences of viral vector belonging to RG 1.<br>Research involving the introduction of nucleic acids into animals provided that the nucleic acid does not give rise to any infectious agent. | Research & development, and maintenance of GE plants harboring DNA from Risk Group 1 microorganism.<br>Working with plants for the development/ improvement of transformation protocols.<br>Genome editing leading to SDN1-type mutations. | An investigator should intimate the IBSC of the study objectives and experimental design along with organisms involved.<br>IBSC should review the same as and when convened for record purpose, monitoring or action to be taken, if any. |

# Submission of applications

## BSL2 category

| S.No. | GE experiments on | | | Approvals |
|---|---|---|---|---|
| | **Microorganism** | **Animals** | **Plants** | |
| Category 2 | Work with nonapproved host/vector systems where the host or vector does not cause disease in plants, humans or animals.<br>Experiments with approved host/vector systems, in which the gene inserted is a pathogenic determinant.<br>Experiments on RG2 microorganisms in the presence of helper virus experiments in which DNA from RG2 or 3 organism is transferred into nonpathogenic prokaryotes or lower eukaryotes host vector system. | Experiments with GE animal and associated materials, harbouring DNA from a RG 2 microorganism.<br>Experiments with animals infected with GE microorganism (s) that fall under Risk Group 2. | Research & development, and maintenance of GE plants harbouring DNA from Risk Group 2 microorganism.<br>Experiments on GE plants conferring herbicide tolerance or pathogen resistance.<br>Genome editing leading to SDN 2 and 3 -type modifications. | An investigator requires Prior authorization from IBSC before the commencement of the experiments. |

# Submission of applications

## Category of experiments, GE organism involved and Biosafety Level Facility Requirements

| Category | GE Microorganisms | GE Animals | GE Plants |
|---|---|---|---|
| Category 1 | BSL-1 | ABSL-1 | PBSL-1 |
| Category 2 | BSL-2 | ABSL2 | |

Examples of BSL2 microorganisms

Bacteria: *Staphylococcus aureus*, *Salmonella* species, *Shigella* species, and pathogenic strains of *Escherichia coli*.
Viruses: Human Immunodeficiency Virus (HIV), Hepatitis B and C viruses, Herpes simplex viruses, and Measles virus.
Parasites: *Plasmodium falciparum* and *Toxoplasma* species.

# IBSC Assessment (Main aspects)

| Broad categories data requirement | Information Required |
|---|---|
| **Molecular Biology Details** | |
| Characteristics of source (donor) organisms | • Origin/source and taxonomic classification<br>• Nature of pathogenicity and virulence, infectivity, allergenicity and toxicity, its host range and stability of these traits |
| Characteristics of host/recipient organisms | • Origin/source and taxonomic classification<br>• Specific genotypic characters<br>• Information on reproductive biology, including, growth and development, reproductive cycle (asexual/sexual) details. For plants, information on floral biology, seed dormancy and dissemination of seeds.<br>• Nature of pathogenicity and virulence, infectivity, allergenicity and toxicity, its host range and stability of these traits<br>• Degree of relatedness including evidence of exchange of genetic material between donor and recipient organisms or any other Organisms |

# IBSC Assessment (Main aspects)

| Broad categories data requirement | Information Required |
|---|---|
| **Molecular Biology Details** | |
| Characteristics of gene construct | • Description of all genetic materials used for modification of GMO, including, their sources, sizes, coding and non-coding regions, orientation, etc., modification(s) (e.g., codon optimization, amino acid substitution, truncation of transgenes) if any, made in native DNA sequence (from the source organism) of the genetic elements etc.<br>• Physical map (including coding regions, promoters and enhancers, marker genes, antisense genes)<br>• Nucleotide sequence of intended insert and its function/s |

# IBSC Assessment (Main aspects)

| Broad categories data requirement | Information Required |
|---|---|
| **Molecular Biology Details** | |
| Characteristics of host/recipient organisms | • Origin/source and taxonomic classification<br>• Specific genotypic characters<br>• Information on reproductive biology, including, growth and development, reproductive cycle (asexual/sexual) details. For plants, information on floral biology, seed dormancy and dissemination of seeds.<br>• Nature of pathogenicity and virulence, infectivity, allergenicity and toxicity, its host range and stability of these traits<br>• Degree of relatedness including evidence of exchange of genetic material between donor and recipient organisms or any other Organisms |

# IBSC Assessment (Main aspects)

| Broad categories data requirement | Information Required |
|---|---|
| **Molecular Biology Details** | |
| Characteristics of vector and method of Transformation | • Nature, source and function of vector<br>• Method of transformation and detailed description of transfer method<br>• Selection method for transformant<br>• Type of insertion (complete or partial) and number of integration sites<br>• Confirming integrity and fidelity of the insert<br>• Determining production of fusion protein and its location in recipient organism |

# IBSC Assessment (Main aspects)

| Broad categories data requirement | Information Required |
|---|---|
| **Molecular Biology Details** | |
| Characteristics of transformed/ modified organism | • Genotypic characters including characterization of site of modification of recipient genome regulation and stability of inserted DNA, frequency of mobilization of inserted DNA and/ or genetic transfer capability<br>• Phenotypic characters including taxonomic characterization, colonization potential, antibiotic resistance, infectivity, production of toxins, allergens, antinutrients or any other metabolites and its host range<br>• Expression and properties of the gene product including copies /number of new gene(s), rate and level of expression, activity of expressed protein, allergenic/toxic hazards of the product<br>• Confirmation of inheritance of new trait(s) over multiple generations |

# IBSC Assessment (Main aspects)

| Broad categories data requirement | Information Required |
|---|---|
| **Human and Health considerations** | |
| Key Components | • Changes in the level of key nutrients, natural toxicants or antinutrients, secondary metabolites, physiologically active (bioactive) substances, etc. |
| Toxicity | • Comparison of the amino acid sequence homology of the newly expressed protein with the known protein toxins and antinutrients<br>• Animal toxicity studies |
| Allergenicity | • Comparison of the amino acid sequence homology of the newly expressed protein to known protein allergens<br>• Heat stability and susceptibility of the expressed protein to<br>• pepsin digestion<br>• Studies such as immunoreactivity assessment, skin sensitization in animals, if required |
| Nutritional Analysis | • Changes in the level of key nutrients, natural toxicants or anti nutrients, secondary metabolites, physiologically active (bioactive) substances, etc. |

# IBSC Assessment (Main aspects)

| Broad categories data requirement | Information Required |
|---|---|
| **Environmental considerations** | |
| Considerations | • Changes in the growth, habit, life cycle, biomass and reproductive characteristics, response to biotic and abiotic stresses, changes in aggressiveness potential and weedy characters, non-target adverse effects etc.<br>• Disposal of biological material |

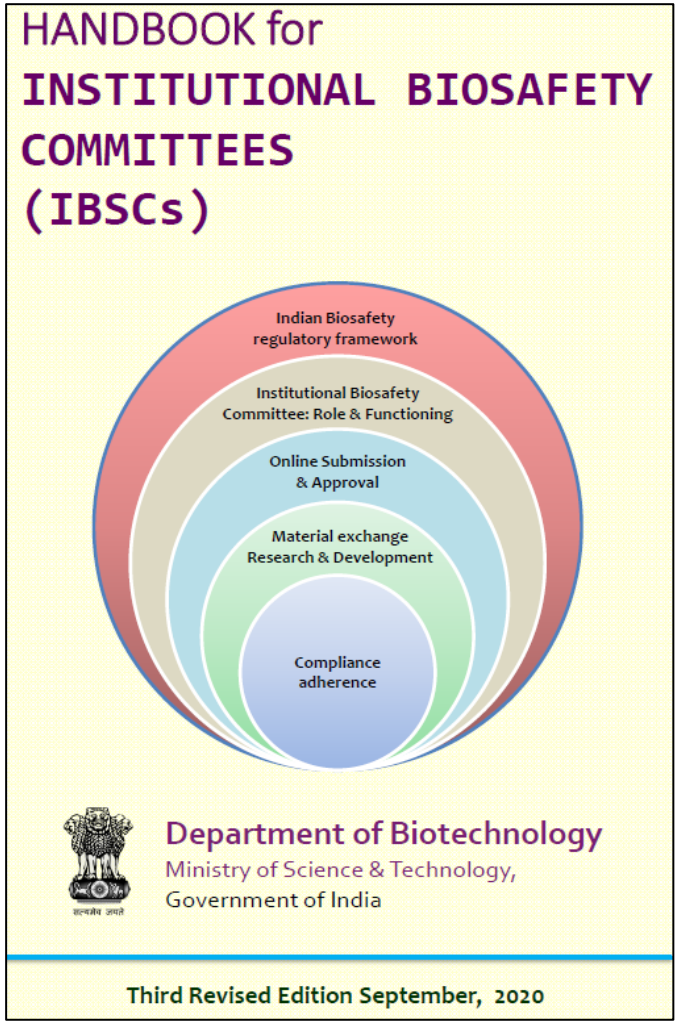
# IBSC Assessment (Main aspects)

## Risk group (RG) classification

| Risk Group (RG) | Description |
|---|---|
| RG 1<br>(no or low individual and community risk) | Microorganism that are unlikely to cause human/ animal/plant disease |
| RG 2<br>(moderate individual risk, low community risk) | Microorganism that can cause disease in human /animal/ plant. Laboratory exposures may cause serious infection, but effective treatment and preventive measures are available and the risk of spread of infection is limited |

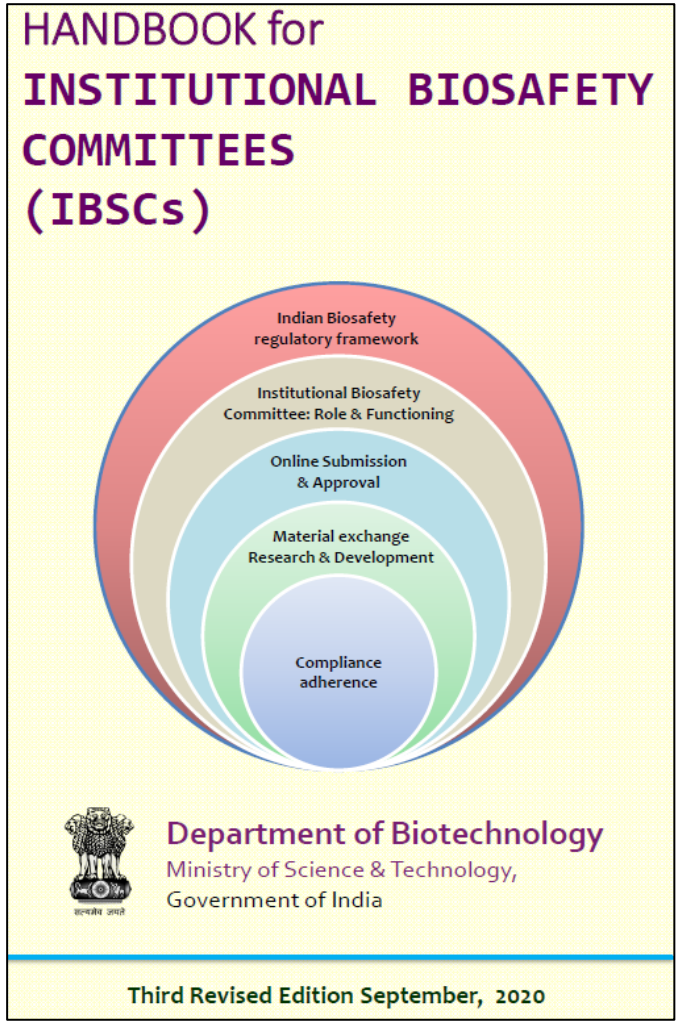
# IBSC's expectations from PIs

- Completely informed of Biosafety regulations
- Completely aware of the details needed to be furnished in an application
- New PIs can seek advise from internal members but should first consult the online example given and approach with genuine questions
    - If a new PI has a senior experienced collaborator (which is often the case), they should take help from their collaborators
    - IBSC does not correspond with your Ph.D. students



# IBSC's expectations from PIs

- Doesn't alter the application after approval
- Should get the application completed (including revisions) and signed by the IBSC chairman within two weeks of intimation
- Should plan well ahead to get an approval
    - The main delays of giving signed approvals is because of many avoidable revisions
    - IBSC does not provide any documents prior to approval by the committee just because a funding agency requires



# Main activities

Communications with RCGM

- Annual transaction record
  - Requires accurate information of the amounts of exchanged materials from the PIs (Based on import/export forms)
- Medical surveillance report
  - Requires reports from the individual PIs
- Annual compliance report
  - Requires coordination from the PIs

# Dos and Don’ts

- Follow the IBSC handbook and be thorough with the requirements
  - Determine which category your research falls into (BSL1 or BSL2 or both)
  - Provide complete and accurate information as per the word limits
    - If additional information needs to be given, you can include in the appendix (but the application should have all necessary information within the word limits
  - Form C1/D1 is an R&D application and requires supporting information about the acquisition of the materials involved in the project (plasmids, proteins, cell lines, etc.). Without this information, the Form C1/D1 may be rejected

# Dos and Don’ts

- Ensure that you are the right person to submit the IBSC application. Forms submitted by wrong persons will be rejected
  - If you are unable to determine if you are the right person to submit, contact IBSC
- The example Form C1 available online is only a guideline
- The procedures to be followed may vary and be quite different from the online example
  - Determine the right procedures to be followed
  - Approach IBSC if it is not still clear
- Some IBSC approvals require prior approvals from IEAC and/or IHEC
  - Applications without these prior approvals will be rejected

# Dos and Don’ts

- Applications cannot be altered after they have been approved in the IBSC meeting.
  - Some examples
    - Biosafety levels mentioned in the application
    - Adding new information that alters biosafety levels
- IBSC will not interact with any other person than the PI who is the faculty responsible for the project and the applications
- Faculty are responsible to ensure that the personnel are adequately trained (so called Biosafety training) for their respective labs

# Dos and Don’ts

- Beginning August 2026, IBSC has brought some changes based on its experiences
    - The submitting PI is completely responsible for the information provided in the application
        - IBSC handbook and the filled Forms have sufficient information to guide the PI
        - If a PI is submitting a form for the first time and is unable to fill it despite going through the examples and the guidelines, then he/she can seek IBSC’s help

# Thank you

IBSC Website
https://www.bits-pilani.ac.in/hyderabad/ibsc
Email:
ibscbitshyd@hyderabad.bits-pilani.ac.in