

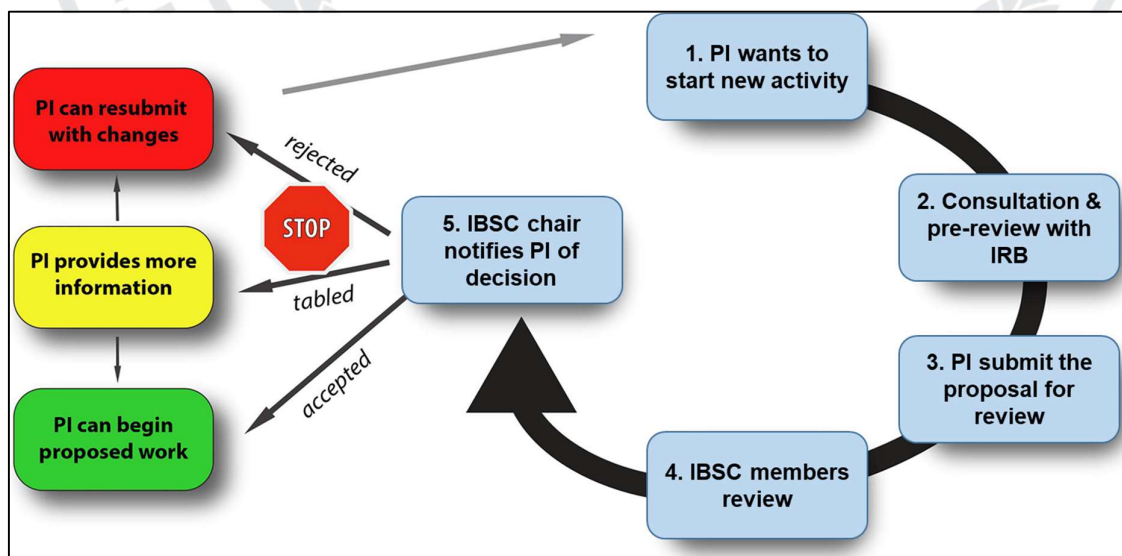


Research and Development Centre

Proposal for Establishing and Registering an Institutional Biosafety Committee (IBSC) to Ensure Regulatory Compliance in Research.

- ✚ Under the Environment Protection Act of 1986 and its associated Rules of 1989, any organization conducting research or applications involving genetically engineered organisms or hazardous microorganisms is required to form an IBSC.
- ✚ This requirement applies to work with a broad range of biological entities, including:
 - ✓ **Genetically engineered organisms:** microorganisms, animals, plants, arthropods, and aquatic species
 - ✓ **Hazardous microorganisms:** parasites, protozoa, algae, fungi, bacteria, viruses, and prions
 - ✓ **Products derived from these organisms**
- ✚ The IBSC serves as the institutional oversight body to ensure compliance with biosafety regulations for organizations engaged in research, use, import, export, or storage of these biological materials.

Institutional Biosafety Committee review process.



ROLES/ RESPONSIBILITIES OF IBSC MEMBERS

Chairperson, IBSC

- ✓ Has awareness of all requirements regarding compliance with the Rules, 1989 and other regulations related to HMOs/GMOs/LMOs/ and products derived thereof and ensure that the biosafety guidelines are followed in their organisation.
- ✓ Ensures that the available facilities at the organisation are adequate to meet the biocontainment levels stipulated while working with Hazardous microorganisms and GE organisms as per the latest guidelines while approving or forwarding applications.
- ✓ Ensures that training of IBSC members and Laboratory Personnel are being conducted on regular basis.
- ✓ Ensures that regular meetings of IBSC are held to review research projects in the organisation; open discussion takes place amongst the members in the meetings and the views of external members as well DBT nominee are recorded in the minutes. All decisions and approval need to have concurrence of DBT nominee.
- ✓ Ensures on-site biosafety & emergency plan are in place and decontamination & disposal mechanisms for laboratory and biomedical waste are in place as per the latest DBT Guidelines and also in accordance the guidelines issued by Central Pollution Control Board (CPCB) and local authorities.
- ✓ Ensures that in case of any accidental release, the concerned Scientist/Principle Investigator must immediately bring it to the notice of the Chairperson, IBSC who would be responsible for ensuring containment of the released organism(s) and informing the regulatory bodies (RCGM/GEAC) in the stipulated timeframe.

Member Secretary, IBSC

- ✓ Acts as a focal point for compliance with rDNA safety guidelines, good lab practices, biological containment etc.
- ✓ Be responsible for reporting and communication with RCGM with respect to functioning of IBSC in an organization.
- ✓ Ensures to organise regular meetings of IBSC and maintain updated documents such as agenda, minutes of meetings and other related papers for proper record keeping.
- ✓ Ensures that IBSC minutes and applications considered in the meeting are submitted through **IBKP portal within 7 days of meeting**.
- ✓ Ensures that annual reports in the prescribed proforma and medical surveillance reports are submitted at IBKP portal **on or before 15th February of each year**.
- ✓ Provides technical advice to Principal Investigator about safety procedure and containment facility as per the guidelines issued by DBT.

Biosafety Officer

- ✓ Ensures that biosafety measures are in place to prevent the accidental escape of hazardous microorganisms and GE organisms.
- ✓ Wherever there is a BSL3/4 facility, Biosafety officer must be trained to familiarise with BSL-3 and 4 facilities and be responsible for monitoring such facilities and health of workers in the facility.
- ✓ Undertake periodic laboratory inspections specially BSL-3 and BSL-4 facility.
- ✓ Assist Project Investigators (PI) in developing emergency plans for containment and clean-up of investigates, accidental releases, if any etc. and review emergency plans from time to time to prevent any lab accidents.
- ✓ Prepares Medical Surveillance Reports for people working in BSL 3 or 4 facilities in the performa available on IBKP of all laboratory personnel annually and submit to Member Secretary for uploading online at IBKP before commencement of rDNA work by PIs.
- ✓ Review and report to the Head of the organisation and Member Secretary, IBSC, DBT nominee of any non-compliance of guidelines / health issues of staff.

DBT Nominee, IBSC

- ✓ Serves as the link between DBT-RCGM and the respective IBSC
- ✓ Ensures that the IBSC reviews all ongoing activities.
- ✓ DBT nominee must ensure compliance of all relevant guidelines.
- ✓ Ensures that all the activities carried out in the organization are within the purview of the DBT guidelines and guide the IBSC on all biosafety matters including compliances.
- ✓ Includes an assessment report of on-site inspection of the available facilities in the IBSC meetings.
- ✓ If any new pathogen/ higher Risk group organism (RG 3&4) is to be used by the organization, the DBT nominee shall assess the capacity and infrastructure to conduct the experiments in the organisation and include that in the IBSC meeting minutes.
- ✓ In case of any accidental release, the IBSC Chairperson must inform DBT nominee at the earliest. The DBT nominee must then review the safety measures taken and accordingly, send an independent report on the “accidental release” highlighting any non-compliance of guidelines / health issues of staff to the Member Secretary, RCGM within 48 hrs.

Internal and External Members

- ✓ Review all submitted applications as per the guidelines and checklist (refer to Section functions of IBSC).

FUNCTIONS OF IBSCs:

- a) Assess and monitor the items of general consideration i.e. research facilities, procedures and experts involved in HMOs/GMOs/LMOs and GE research and ensure that the proposed risk assessment, risk management and emergency plans are sufficient.

- b) Provide guidance to Principal Investigator on the issues related to biosafety while using HMOs/GMOs/LMOs and GE research including safety of the researcher(s) associated with the work.
- c) Inform the Principal Investigator about IBSC review, approval or rejection of applications.
- d) Copies of site emergency plan to be submitted to RCGM, GEAC, State Biotechnology Coordination Committee (SBCC) or District Level Committee (DLC) as the case may be, as per Rules, 1989e). The IBSC shall inspect laboratories using checklists. IBSC shall apprise short coming measures (if necessary) under information to Head of Organisation. Inspection reports should be maintained in the IBSC.
- e) Reporting for incidents and release: It is necessary that any incident within an organisation such as non-compliance of the biosafety guidelines, any biosecurity issues or any significant research-related accidents and illnesses be reported to IBSC/ RCGM
- o The primary function of the IBSC is to implement and ensure compliance of provisions of Rules 1989 at the Institutional level. These functions include:

Implement	Evaluate/ consider/ review	Report	Approve
- Biosafety guidelines - On site emergency plans - Biosafety Training	- Application/ Activities* - Physical safety and security measures - Applications/ activities for approval	- Compliance to Rules 1989 - Biosafety/ biosecurity threats and management	- Category I/ II Genetic engineering - 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.

- ✓ Participate in the training programs organized by IBSC to train researchers on biosafety and Biosecurity aspects.

Standard Operating Procedure for Biohazards Decontamination, Disposal Mechanism and Risk Management Measures

This proposal outlines a comprehensive framework for managing biological hazards through systematic decontamination protocols, safe disposal mechanisms, and robust risk management strategies. The increasing complexity of biological research, healthcare operations, and industrial biotechnology necessitates stringent safety measures to protect personnel, communities, and the environment from potential biological threats. Our proposed system integrates established scientific principles with cutting-edge technology to create a multi-layered defense against biohazard exposure and contamination.

Biohazardous Waste

Infectious and recombinant material waste management

Infectious waste comprises pathogenic and potentially pathogenic biological agents utilized in research settings. It encompasses biological materials and agents used in laboratory research, including viral and bacterial cultures, human cell lines, tissue specimens, organs, blood and blood products, as well as both live and attenuated vaccines. It also includes all waste generated during the handling and manipulation of these biological agents, such as culture media, serum, agar plates, laboratory consumables, sharps, personal protective equipment like gloves, masks, respirators, eye protection, face shields, gowns, head covers and other contaminated materials.

Whereas, Recombinant DNA (rDNA) biohazards include molecules that are constructed outside living cells by joining natural or synthetic DNA segments of DNA molecules capable of replicating inside living cells. It also includes synthetic DNA segments that are likely to yield a potentially harmful polynucleotide or polypeptide (e.g. a toxin or a pharmacologically active agent). If the synthetic DNA segment is not expressed in vivo as a biologically active polynucleotide or polypeptide product, it is exempt.

All biohazardous waste shall be processed through the established Biohazardous Waste management system. This system requires the categorization and segregation of various waste types to ensure each receives the appropriate handling and disposal treatment according to specific procedures and requirements.

Standard Operating Procedure for the Disposal of Sharp Objects in Laboratories

1. What are Sharps?

Sharp waste includes any device or item with corners, edges, or projections that can cut or pierce skin or waste containers/ disposable bags. Such items pose puncture and contamination risks and require specialized disposal containers to ensure safe handling and prevent exposure to infectious materials. Examples of sharps include:

- Hypodermic needles
- Syringes, including tubing, with or without needles
- Blades (scalpels, razors)
- Sharp dental wires and appliances
- Glass capillary tubes
- Microscope slides and covers contaminated with an infectious agent
- Pasteur pipettes contaminated with an infectious agent
- Serological pipettes contaminated with an infectious agent
- Laboratory glassware contaminated with an infectious agent
- Pipette tips contaminated with an infectious agent
- Laboratory broken plasticware contaminated with an infectious agent

2. Sharps Containers

- All sharps containers **MUST** meet the following standards:
- Rigid
- Non-breakable and puncture-resistant
- Resistant to moisture and leak-proof
- Have a self-closing lid
- Red colour with a universal biohazard label, except for a non-hazardous disposal box



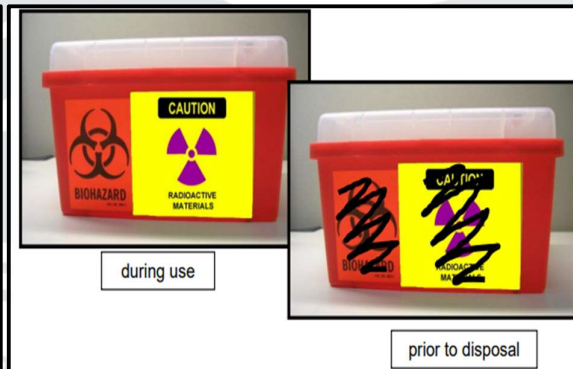
Biological Hazards/ infectious sharp container



Non-hazardous Glass/plastic ware Disposal Box



Chemically contaminated sharp container



Sharps Contaminated with Radioactive Materials

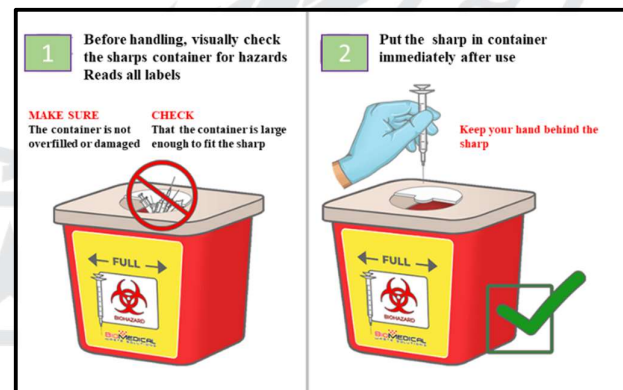
3. Collection Procedures

Sharps containers **MUST**:

- Be stored near where the waste is generated and segregated from other waste
- Have their lids in place while in use

Sharps containers **MUST NOT**:

- be overfilled greater than the 2/3 fill line mark
- be discarded in the regular trash
- contain free liquids, such as full culture tubes or filled syringes



4. Disposal Procedures



Regardless of use, all syringes (with or without a needle attached), needles (hypodermic, suture, with or without attached tubing), blood vials, and cutting instruments (scalpels, razor blades) **MUST** be disposed of in a rigid, puncture-resistant, leak-proof, rigid sharps container lined with a biohazard bag of mandated colour.

All used sharp waste that has been in contact with infectious agents or used in animal/human patient care or exposed to recombinant materials **MUST** be disposed of in a rigid, puncture-resistant, leak-proof, rigid sharps container (Marked with the **BIOHAZARD** symbol and labeled with the word “**SHARPS**”) lined with a biohazard bag of mandated colour. It includes pipettes (Pasteur pipettes, pipette tips, serological pipettes, plastic transfer pipettes), broken or unbroken glassware or broken plasticware (culture dishes, slides, cover slips, Centrifuge tubes, capillary tubes, and other plastic tubes), and other pointed devices capable of punching a

disposable bag.

Non contaminated sharps waste (that has **NOT** come in contact with infectious agents or that has **NOT** been used in animal or human patient care or treatment, or **NOT** exposed to recombinant material or **NOT** contaminated with radioactive material), or radioactive material, **EXCLUDING** all syringes (with or without a needle attached), needles (hypodermic, suture, with or without attached tubing), blood vials, and cutting instruments (scalpels, razor blades) **MAY** be disposed of in a cardboard box with heavy plastic liner or designated sharps container labelled with the word “**SHARPS**”.

- Disposable sharps containers **NEED TO BE AUTOCLAVED** in advance of disposal.
- Used sharps can either be decontaminated and stored in a covered container or disposed of immediately in a designated sharps disposal container as per the above guidelines.
- DO NOT** dispose of syringes and scalpels uncapped.
- DO NOT** dispose of infectious/biohazard sharps through the regular waste stream.
- DO NOT** discard sharps in any bag.
- DO NOT** autoclave chemically contaminated sharps. Instead, label with “Chemical Contaminated Sharps **DO NOT AUTOCLAVE**”, close when container is 75% full and dispose of through the infectious waste stream.
- Laboratory glassware **MUST** be triple rinsed and subsequently disposed of in appropriate glassware disposal containers.
- Containers undergo weekly inspections and will be replaced as needed when they reach 75% capacity or develop odors, or upon request.
- A designated trained employee must autoclave all sharps containers and deposit them in the infectious waste collection bin, excluding any containers marked "Chemical Contaminated Sharps **DO NOT AUTOCLAVE**”.

Disposal of Sharp Objects

Biological Hazard/ Infectious/ rsNA	Chemical contaminated	Radioactive contaminated	Non contaminated glass/plastic ware	Non contaminated sharp

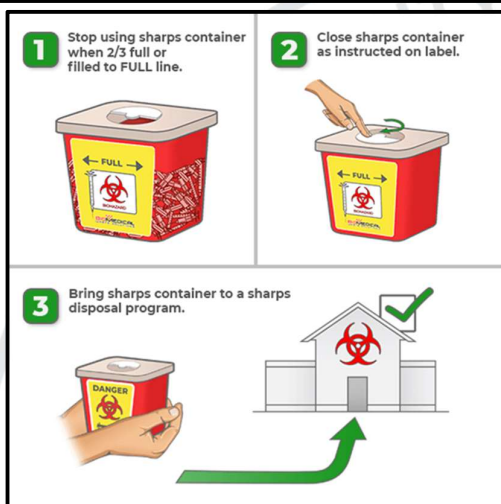
5. 9 Sharps “Do NOTs”

- Do NOT** throw loose sharps in the trash.
- Do NOT** put sharps in recycling bins.
- Do NOT** flush sharps down the toilet.
- Do NOT** keep sharps containers where children can reach them.
- Do NOT** use glass bottles, plastic water bottles, milk jugs or cartons, or soda cans as do-it-yourself sharps containers.
- Do NOT** fill sharps containers past the fill line or three-quarters (3/4) full, and don't force needles inside.
- Do NOT** Put your sharps into the container immediately after use.
- Do NOT** bend or break needles.
- Do NOT** recap others' needles; if you do not have a sharps container, you may want to carefully recap your own needles.

DO NOT Throw loose sharps in trash 	DO NOT Put sharps in recycling bin 	DO NOT Flush down the sharps 	KEEP OUT of children's reach of children 	DO NOT Force sharps into the container
DO NOT Put fingers inside container 	DO NOT Remove needle 	DO NOT Bend or break needle 	DO NOT Recap needle 	

6. Where to Dispose of Sharps Containers?

Types of sharps disposal program at KJU



- ✚ Ensure your sharps containers are labeled correctly.
- ✚ Secure the lid of the disposal container in the appropriate manner as per local guidelines and disposal program.

Standard Operating Procedure for the Disposal of Liquid Waste in Laboratories

1. Liquid waste

Includes all biological media, liquids from petri dishes and culture vials, laboratory equipment, and recombinant nucleic acids in any form—including both natural and synthetic variants such as DNA, RNA, shRNA, and related molecules.

2. Liquid Waste Containers

- ✚ The container **MUST** be leak and puncture proof and **MUST** have lid.
- ✚ A label of “**BIOHAZARD SYMBOLE**” **MUST** be visible on the container.



Liquid Aspirator



Liquid discard bottle

3. Collection Procedures

- ✚ Liquid waste **MUST** be separated and segregated from Solid or Sharps or Radioactive or Chemical waste.
- ✚ **Do not** fill up waste collection bottles more than 75% of their total volume.

4. Disposal Procedures

- ✚ Liquid waste **MUST** be decontaminated on-site using a suitable disinfectant or bleach solution, with adequate contact time for effective treatment.
- ✚ Dispose of the disinfected material by flushing it down the sink with cold running water for at least 5 minutes
- ✚ Liquid waste from biosafety level 2 (BSL-2) and higher containment laboratories **MUST** be sterilized by autoclaving before flushing.
- ✚ **Do not** flush non-aqueous solutions, such as liquefied agarose or unfiltered broths, down the drain to avoid clog the drainpipes.

Standard Operating Procedure for the Disposal of Solid Waste in Laboratories

1. Solid waste

Other waste material produced in the lab that may be potentially infected with biological agents (human, bacterial, animal, Viruses, etc.), or exposed to recombinant material, or exposed to radioactive elements. It includes

- Paper towels
- Gauze
- Wipes
- Absorbents
- Agar gels
- Disposable Personal Protective Equipment (Gowns, Mask, used gloves, Eyewear, face shield shoe cover, head cover etc.)
- Disposable Petri dishes
- Culture vials (flask, multi-well plates)
- Non-sharp plastic consumables (Centrifuge tubes and other plastic tubes, Disposable Filter unit, cell strainer etc.)

- Plants or any parts/ tissues, seeds, soil/soil substitute (perlite, vermiculite, peat mass, etc.)



Solid waste types

2. Solid Waste Containers



Biohazard Containers and Bags

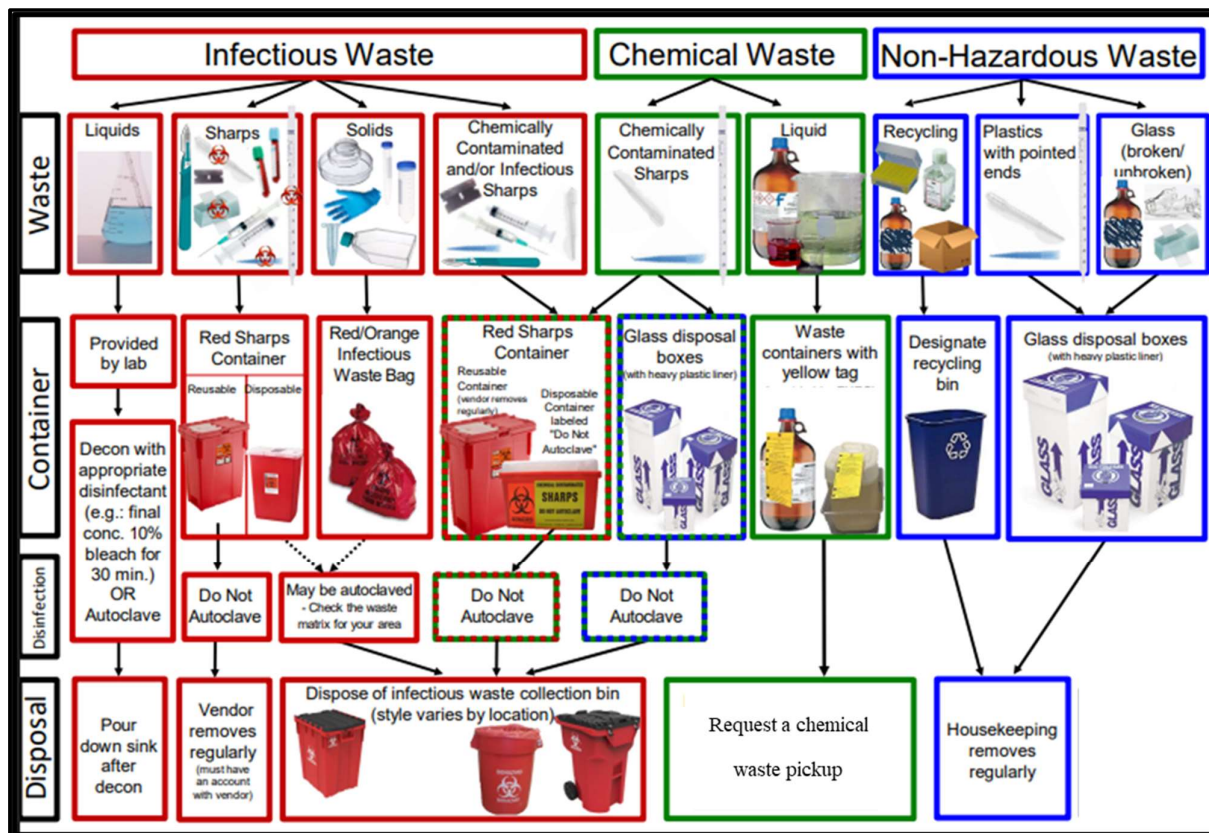
3. Collection Procedures

- ✦ All infectious waste **MUST** be segregated properly at the time of generation.
- ✦ Upon completion of work with biological materials, proper inactivation or decontamination procedures **MUST** be implemented.
- ✦ Solid waste **MUST** be collected in autoclavable biohazard bags contained in a hard-sided, leak proof, lidded container
- ✦ Any bag bearing a biohazard symbol must be treated as infectious waste for disposal, regardless of whether it has been used.
- ✦ **DO NOT** autoclave biological waste contaminated with chemicals
- ✦ **DO NOT** discard any infectious waste through the regular waste stream.
- ✦ **DO NOT** overfill (The biohazard bag should be 3/4th fill maximum)
- ✦ **DO NOT** put materials on lid.
- ✦ To transport container(s) outside the facility for decontamination, ensure that the biohazard bag is sealed and the lid is tightly closed.
- ✦ A trolley for transport is preferred. **DO NOT** toss

4. Disposal Procedures

- ✦ All solid hazardous waste **MUST** be autoclaved
- ✦ A designated trained employee **MUST** autoclave all solid waste bag/containers and deposit them in the infectious waste collection bin, excluding any containers marked "Chemical Contaminated Sharps" **DO NOT AUTOCLAVE**
- ✦ Prior to autoclaving, crisscross the bag's biohazard symbol and/or markings with heat sensitive autoclave tape.
- ✦ Ensure the autoclave is set for the appropriate time– selection of time and pressure should ensure proper decontamination. For e.g. Organism containing TSE must be autoclaved at a higher setting.
- ✦ Once the waste is autoclaved, mark the autoclaved bag with an "Autoclaved/Decontaminated" sticker.
- ✦ Place the autoclaved bag into an opaque bag of mandated colour and seal it.
- ✦ Store the bag in a place that could be collected for disposal by cleaning personnel or after autoclaving infectious waste MAY be properly packaged for removal or incineration.

Biohazard Waste Disposal Guide



Know Where to Throw Lab Waste

Sharps Containers	Biohazard Bags	Glass Disposal Box
 - ALL needles, syringes (with/without the needle), and blades - Infectious (or potentially infectious) pipette tips, serological pipettes, blood vials, slides/cover slips, other glass - Nominal contamination with chemicals 	 - Infectious (or potentially infectious) disposable items - culture flasks, dishes, centrifuge tubes, specimen bags, PPE, - Items with a biohazard symbol 	 - Non-infectious/Non-hazardous items - Pipette tips, serological pipettes, broken/unbroken glass, slides/cover slips, other pointy items, and empty chemicals bottles (triple rinsed) - Nominal contamination with chemicals 

Risk Assessment:

Laboratories should use a risk-evaluation/assessment method that best meets their unique needs. A template for this will be provided to PIs involved in the research handling genetic engineering organism or organism under risk group 2 and above. The investigators need to assess the risk and the answer the queries in this template. Risk will be evaluated as a function of consequence of hazard (**Table 1**) and its possibility of exposure (**Table 2**) to people and environment. All the risks will be classified into four categories (**Table 3**) depending on severity and appropriate containment level will be selected accordingly.

Table 1: Consequence assessment

Marginal	- Minimal adverse health effects. - Minimal or no damage to the environment or disruption to biological communities.
Minor	- Adverse health effects that is reversible. - Damage to the environment or disruption to biological communities that is reversible and limited in time and space or numbers affected.
Intermediate	- Adverse health effects that is irreversible. - Damage to the environment or disruption to biological communities that is widespread but reversible or of limited severity.
Major	- Adverse health effects those are severe, widespread and irreversible. - Extensive damage to the environment or extensive biological and physical disruption of whole ecosystems, communities or anentire species that persists over time or is not readily reversible.

Table 2: Likelihood assessment

Likelihood	Definitions.
Highly unlikely	May occur only in very rare circumstances.
Unlikely	Could occur in some circumstances.
Likely	Could occur in many circumstances.
Highly likely	Is expected to occur in most circumstances.

Table 3: Risk categorization approach

Likelihood	Consequence			
	Marginal	Minor	Intermediate	Major
Highly unlikely	Low	Moderate	High	High
Unlikely	Negligible	Low	High	High
Likely	Negligible	Low	Moderate	High
Highly likely	Negligible	Negligible	Low	Moderate

Risks **MUST** be evaluated on parameters described below:

A. Assessment of effect on human health

- ✓ Expected toxic or allergenic effects of the GE organism and/or its metabolic products.
- ✓ Comparison of the GE organism to the recipient or (where appropriate) parental organism.
- ✓ Pathogenicity.
- ✓ Capacity for colonisation.
- ✓ Diseases caused and mechanism of transmission including invasiveness and virulence.
- ✓ Infective dose.
- ✓ Possible alteration of route of infection or tissue specificity.
- ✓ Possibility of survival outside human host.
- ✓ Biological stability.

- ✓ Antibiotic-resistance patterns.
- ✓ Allergenicity.
- ✓ Toxigenicity.
- ✓ Availability of appropriate therapies and prophylactic measures.

B. Information on recipient organism

- ✓ Taxonomy, identification, source, culture.
- ✓ Nature of pathogenicity and virulence, infectivity, allergenicity, toxicity and vectors of disease transmission.
- ✓ Nature of indigenous vectors and adventitious agents, where they could mobilise the modified organism, and the frequency of mobilisation.
- ✓ Nature and stability of genetic modification, if any.
- ✓ History of prior genetic modification, if any.
- ✓ Information on natural occurrence.
- ✓ Information on possible spread of recipient organism and its progeny in the absence of confinement.
- ✓ Host range (if relevant).
- ✓ Information on ecological functions of recipient organism.
- ✓ Information on the potential of organism to establish itself in the accessible environment.
- ✓ Ability to form survival structures (such as spores).
- ✓ History of safe use, if any.

C. Information on process of genetic modification

- ✓ The nature, function and source of the inserted donor nucleic acid, including regulatory or other elements affecting the function of the DNA and of the vector.
- ✓ Purpose and method of genetic transformation and procedure followed for selection of the modified organism.
- ✓ Any possible dual usage that may compromise health and safety of people and environment.
- ✓ Rate and levels of expression of the introduced genetic material.
- ✓ Function of the expressed protein(s).
- ✓ The structure and amount of any vector and/or donor nucleic acid remaining in the final construction of the modified organism.
- ✓ Characterisation of the site of modification of the recipient genome and sequence confirmation of the introduced genetic elements for the accuracy of modification and for intended function.
- ✓ Stability of the genetic modification (inserted DNA).
- ✓ Similarity of the expressed recombinant protein with potential known toxin and/or allergen.
- ✓ Kinetics and level of expression of inserted genetic material.

D. Assessment of effect on environment

- ✓ Routes by which the GE organism could be released (including waste disposal, equipment failure and human spread).
- ✓ Potential to infect or colonise animals and plants.
- ✓ The local environment surrounding the containment facility as well as the wider environment, especially if there is a possibility that the GE organism could survive and disseminate.
- ✓ Expected survivability, multiplication and extent of dissemination of the GE organism in the identified ecosystems.
- ✓ Anticipated result of interaction between the GE organism and the organisms or microorganisms which might be exposed in case of unintentional release into the environment.

- ✓ Known or predicted effects on humans, plants and animals such as pathogenicity, toxicity, allergenicity, vector for a pathogen, altered antibiotic-resistance patterns, altered tropism or host specificity, colonisation known or predicted involvement in biogeochemical processes.

Note:

- ✚ Experiments, handling and use of organisms/ products derived from genetic engineering require added precaution for which experiments must be monitored at the institution level by IBSC and other competent regulatory authorities.
- ✚ All genetic modification risk assessments should be reviewed regularly and be updated in the light of new scientific knowledge or where there has been a change in the nature of the activity (including a change in scale or any new procedures and containment measures).
- ✚ All experiments on genetic engineering must be properly documented and audited. All data should be recorded and must be available to the competent regulatory agencies whenever asked on demand, for risk assessment. It is the responsibility of investigator to maintain records and later by the institution for at least 6 years after the work has ceased (storage of materials is also considered to be active work in this case).
- ✚ Efficiency of decontamination and disposal mechanisms should be discussed and adopted accordingly. Specific measures may be required and must be developed on case by case basis over and above those mentioned in this guideline. IBSC will ensure that the measures are sufficient for containment and are recorded and informed to all personnel working in the facility.

Risk Assessment Template

Institution/ Facility name	
Laboratory Name	
Laboratory manager/ Supervisor	
Project title/ Relevant standard operating procedure (SOPS)	
Date	
Hazard Identification	
<i>Instruction: Provide a brief overview of laboratory work and summarize the laboratory activities to be conducted that are included in the scope of risk assessment.</i>	
Describe the biological agents and other potential hazards (for example: transmission, infectious dose, treatment/prevention measures, pathogenicity)	
Describe the procedures to be used (for example: culturing, centrifugation, work with sharps, waste handling, frequency of performing the laboratory activity)	
Describe the type of equipment to be used (for example: personal protection equipment (PPE), centrifuges, autoclaves, Biosafety cabinets)	
Describe the type and condition of the facility where work is conducted	
Describe relevant human factor (for example: competency, training, experience and attitude of personnel)	
Describe any other factor that may affect laboratory operation (for example: legal, cultural, socioeconomic)	

Evaluate the Risk	
Instruction: Describe how exposure and or release could occur	
What potential situation are there in which exposure or release could occur	
What is the likelihood of an exposure/release occurring • Highly unlikely: May occur only in very rare circumstances • Unlikely: Could occur in some circumstances • Likely: Could occur in many circumstances • Highly likely: Could occur in many circumstances	
What is the severity of consequences of an exposure/release (Negligible, Low, Moderate, High)	
Develop a risk control strategy	
Are resources sufficient to secure and maintain potential risk control measures?	
What factors exist that may limit or restrict any of the risk control measures?	
Will work be able to proceed without any risk control measures; are there alternatives?	
Instruction: Describe how to communicate risk and risk mitigation strategies to personnel. Provide a mechanism of communication within the laboratory. Describe the process and timeline for ensuring that all identified risk control measures are purchased and have associated SOPs and training has been completed before starting the laboratory work	
Communication of the hazards, risks, and risk control measures	
Purchase (and budgeting) of risk control measures	
Operational and maintenance procedures	
Training of personnel	
Instruction: Establish a periodic review cycle to identify: changes in laboratory activities, biological agents, personnel, equipment, changes in knowledge of biological agents or process, and lessons learnt from the audits/inspections, personnel, feedback, incidents, and/or misses	
Frequency of the review	
Person to conduct the review	
Describe updates/changes	
Reviewed by (Name and title)	
Reviewed by (Signature)	
Date	
Place	

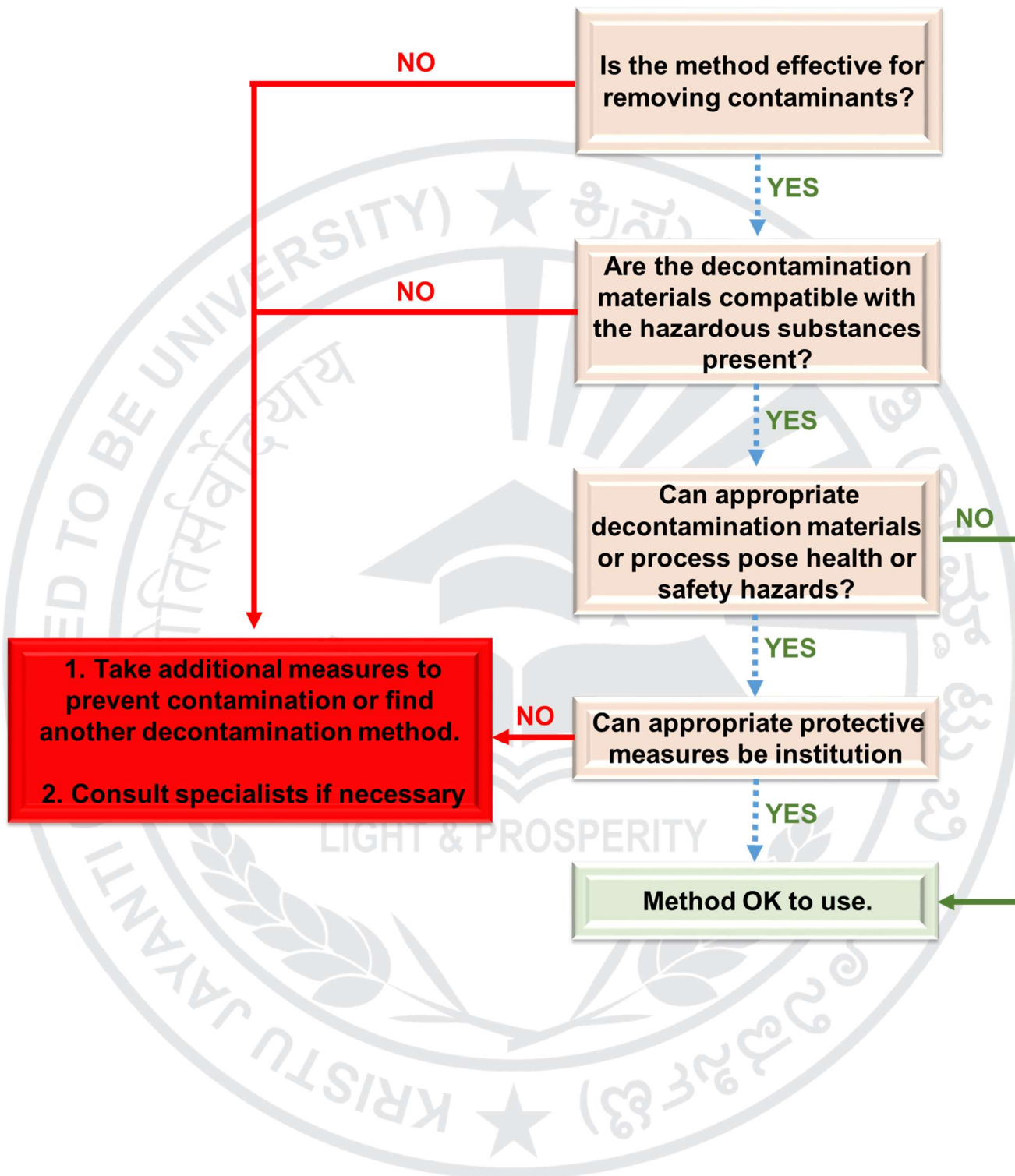
Bio-Medical Waste Management Rules

Biomedical wastes categories and their segregation, collection, treatment, processing and disposal options

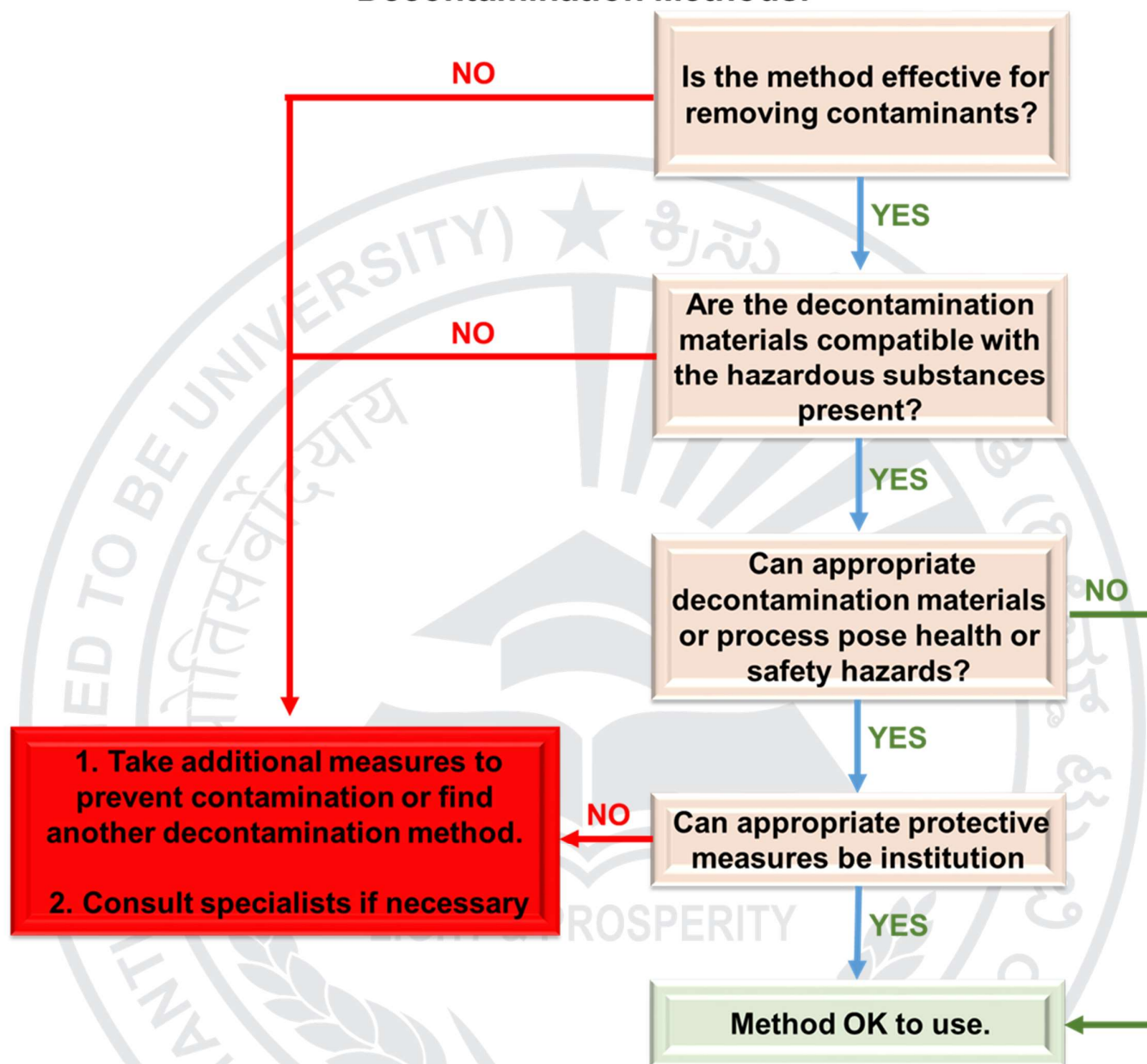
Category	Type of Waste	Type of Bag or Container to be used	Treatment and Disposal options
Yellow 	a) Human Anatomical Waste b) Animal Anatomical Waste c) Soiled Waste d) Expired or Discarded Medicines e) Chemical Waste f) Discarded linen, mattresses, beddings contaminated with blood or body fluid, routine mask and gown	Yellow coloured non-chlorinated plastic bags or containers	Incineration or Plasma Pyrolysis or deep burial* The discarded medicines shall be either sent back to manufacturer or disposed by incineration
	g) Micro, Bio-t and other clinical lab waste	Autoclave safe plastic bags or containers	
	h) Chemical liquid Waste	Separate collection system leading to effluent treatment system	After resource recovery, the chemical liquid waste shall be pre-treated before mixing with other wastewater
Red 	Contaminated Waste (Recyclable)	Red coloured nonchlorinated plastic bags or containers	Autoclaving or micro-waving/ hydroclaving followed by shredding or mutilation or combination of sterilization and shredding. Treated waste to be sent to recyclers. Plastic waste should not be sent to landfill sites.
White (Translucent) 	Waste sharps including Metals	Puncture proof, Leak proof, tamper proof containers	Autoclaving or Dry Heat Sterilization followed by shredding or mutilation or encapsulation in metal container or cement concret
Blue 	Glassware and Metallic Body Implants	Puncture proof and leak proof boxes or containers with blue coloured marking	Disinfection or through autoclaving or microwaving or hydroclaving and then sent for recycling

Source: Bio-Medical Waste Management Rules, 2016 and amended rules 2018

Decision Aid for Evaluating Health and Safety Aspects of Decontamination Methods.



Decision Aid for Evaluating Health and Safety Aspects of Decontamination Methods.





MEDICAL SURVEILLANCE REPORT

1. Personal Details

- i. Name of the Organisation :
- ii. DBT Office Memorandum No. :
- iii. Name of the personnel :
- iv. Designation :
- v. Department :
- Phone :
- Email :
- DOB :

2. Contact with products of rDNA Technology

Please indicate rDNA products, tissue, blood, or biological agents that you work with (tick yes or no):

- i. Do you work with recombinant DNA technology? If yes, please specify

Yes ☐ No ☐

- ii. What is the biosafety containment level requirement of organisms handled by you?

BSL-1 ☐ L-IBS ☐ BSL-2 ☐ BSL-3 ☐ BSL-4 ☐

- iii. Do you work with human blood products or human tissue? If yes, please specify

Yes ☐ No ☐

iv. Do you work with animal blood products or animal tissue? If yes, please specify

Yes ☐ No ☐

3. Medical History

i. Have you had any change in your health status in the previous year? If yes, please describe

Yes ☐ No ☐

ii. Have you developed any chronic illness in the past year? If yes, please describe

Yes ☐ No ☐

iii. Have you developed any new allergies in the past year? If yes, please describe

Yes ☐ No ☐

iv. Have you been told by a physician that you have an immune compromising medical condition or are you taking medications that impair your immune system (steroids, immunosuppressive drugs, or chemotherapy)?

Yes ☐ No ☐

4. If yes to any of the above, please attach a medical surveillance report certified and signed by the registered medical practitioner in the following format:

- i. Date of health surveillance:
- ii. Test or examinations performed and results



KRISTU JAYANTI
(DEEMED TO BE UNIVERSITY)
Under Section 3 of UGC Act 1956
A CMI INSTITUTION | BENGALURU | INDIA

Research and Development Centre

APPLICATION FOR INSTITUTIONAL BIOSAFETY COMMITTEE (IBSC) APPROVAL

(A scan copy of the completed application form and supporting documents must also be sent to the Secretary, IBSC. **This application form should be typed and not handwritten**)

To
The Member Secretary
IBSC, Kristu Jayanti Deemed to be University
K NarayanaPura
Bangalore-77

(To be forwarded through Head of the Department)

I am here by submitting the required details of the research work (sanctioned research project/PhD research/Dissertation work/in-house research work etc) for approval by IBSC

1. Name of the Applicant:
Official Address:
Contact No:
E-mail:
2. Name of Co-PI, if any:
Official Address:
Contact No:
E-mail:
3. Name of Supervisor:
Official Address:
Contact No:
E-mail:
Department & Enrolment no of student:
4. Title of the research work:
5. Funding agency (if any):
6. Category of research work (✓ the appropriate one)
 - a. Approved/sanctioned external research project
 - b. Approved/sanctioned inhouse project
 - c. PhD work
 - d. UG/PG Dissertation Project

7. Abstract of the research work:
8. Objectives of the research work:
(Specify institution wise if project is multi-institutional)
9. Detail methodology to be used (supported by a copy of synopsis for PhD/Dissertation work and complete research proposal for inhouse/externally funded research project):
10. Tentative date to start the Project/Mention date if already initiated:
11. **Please Specify (in detail) the following:**
 - (i) Specify the work component for which IBSC approval is required:
 - (ii) Risk group of organisms involved, if any:
 - (iii) The containment facility required, if any:
 - (iv) Required Biosafety level as per guidelines:
 - (v) Details of existing facility and expertise available with the PI/Supervisor to adhere to the regulations and biosafety guidelines:
12. Detailed methodology to be used for disposal of biological and hazardous waste to be generated during the research work (if any):

Declaration

I do hereby declare that the above information provided are true to the best of my knowledge and belief. I understand and will adhere (if applicable) to the points specified under 4.2(b) of the hand book of IBSC, 3rd revised edition September 2020, for compliance.

Signature of applicant with Date and Stamp

Details of Supporting Documents to be attached with this form (as applicable)

1. A copy of synopsis duly endorsed by concerned PhD guide
2. Complete research proposal as accepted for funding (inhouse or external).
3. Copy of acceptance letter/sanctioned order of the project (inhouse/external)
4. Any other supporting doc.

Note: use extra sheets if needed