St. John's
National Academy of Health Sciences

ST. JOHN'S NATIONAL ACADEMY OF HEALTH SCIENCES
ST. JOHN'S RESEARCH INSTITUTE
(A Unit of CBCI Society for Medical Education)

INSTITUTIONAL BIOSAFETY COMMITTEE

Sarjapur Road,
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Tel: +91-80-4946 7001
E-mail: ibsc@sjri.res.in

INSTITUTIONAL BIOSAFETY POLICY

Introduction to IBSC:

St. John's National Academy of Health Sciences has duly constituted an Institutional Biosafety Committee (JOHNRES-882)) in alignment with the guidelines prescribed by the Department of Biotechnology (DBT), Government of India. The committee is entrusted with the responsibility of facilitating the implementation of biosafety protocols to ensure the safe handling and use of Genetically Modified Organisms (GMOs) and their derivatives, thereby safeguarding both personnel and the environment.
Please find below the list of reconstituted IBSC Members w.e.f 1st September 2025 –(OM dated BT/IBKP/151/2020-Dated: 02-Sep-2025)

SI. IBSC Committee Members No.

1. Dr. Tony DS Raj -Chairman
2. Dr. Shivaraj BM - DBT Nominee
3. Dr. Madhumathy G Nair -Member Secretary
4. Dr. Parvinder Kaur -Outside Expert
5. Dr. Anil Vasudevan -Biosafety Officer
6. Dr. Mary Dias -Internal Member
7. Dr. Jyothi Prabhu -Internal Member
8. Dr. Neha Vyas -Internal Member

Purpose of IBSC-SJNAHS:

The Institutional Biosafety Committee (IBSC), SJRI, shall be responsible for implementing and overseeing compliance with all applicable rules, regulations, and guidelines pertaining to biosafety. The Committee shall monitor biosafety aspects of research, large-scale experiments, production activities, field releases, exchange (including inter-state and inter-institutional transfer within India), as well as import and export activities undertaken at SJRI and at institutions engaged in collaborative research with SJRI.
These activities include, but are not limited to, the manipulation of genetic material, microorganisms, plants, and animals; and the handling, utilization, storage, and transport of hazardous microorganisms, genetically modified organisms/living modified organisms (GMOs/LMOs), cells, and their products.
The IBSC shall ensure that all such activities are conducted in accordance with the provisions of the Rules, 1989 (Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms/Genetically Engineered Organisms or Cells- Download here) and the guidelines issued by the Department of Biotechnology (DBT) from time to time. IBSC will report and communicate with RCGM with respect to functioning of IBSC at SJRI.

Scope of IBSC-SJNAHS:

All researchers and Principal Investigators (PIs), including faculty, scientists, and students at SJNAHS (and institutions collaborating with SJNAHS), who are engaged in or propose to undertake research activities-such as PhD work, dissertation projects, externally funded projects, and in-house core projects, as well as large-scale experiments,

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production, or field release activities, shall mandatorily inform and obtain prior approval/clearance from the IBSC, SJRI.

This requirement applies to all activities involving the manipulation, handling, utilization, storage, transport, and shipment [including exchange (inter-state and inter-institutional supply/receipt within India), as well as import and export] of regulated biological materials.
IBSC may associate/ invite qualified experts/ consultants from within or outside organisation as and when required to seek advice on specific scientific/ technical matters.

IBSC-SJNAHS - Regulatory Framework:

The regulation of GMOs and their products in India is governed by the "Rules for the Manufacture, Use, Import, Export, and Storage of Hazardous Microorganisms/Genetically Engineered Organisms or Cells, 1989" (hereinafter referred to as the "Rules, 1989"- Download here), notified under the Environment (Protection) Act, 1986- Download here by the Ministry of Environment, Forest and Climate Change (MoEFCC), Government of India.
These rules are complemented by the "Regulations and Guidelines for Recombinant DNA Research and Biocontainment, 2017- Download here" issued by the Department of Biotechnology (DBT), which aim to ensure personnel and environmental safety in the research, manufacture, and application of GMOs.
Further, the "Handbook for Institutional Biosafety Committees (IBSC), 2020 Download here" supersedes the earlier "Guidelines and Handbook for IBSCs" issued in 2011 Download here, and shall be followed for the constitution, roles, and functioning of IBSCs.
The IBSC shall maintain strict confidentiality of all proposals and related information submitted for review, reference, or discussion, and shall not disclose any confidential, intellectual property (IP), or commercial business information (CBI) pertaining to the applicant, organization, or institute obtained during the review process or subsequent deliberations.

Procedure for Submission and Review of IBSC Proposals:

1. IBSC Meetings
The Institutional Biosafety Committee (IBSC), SJRI, shall convene at least two scheduled meetings in a calendar year, typically in mid-June and mid-December. These meetings shall be held mandatorily, irrespective of the number of applications received. Additional meetings may be convened, or appropriate action may be taken, in case of urgent or emergency requirements.
2. Scope of Submission
All research activities involving hazardous microorganisms (Risk Category 1 and above), genetic manipulation, genome editing, cell culture, and/or import, export, or transfer of biological materials or organisms shall require IBSC intimation and/or approval. Where applicable, such proposals may be further reviewed or processed through statutory bodies such as RCGM/IBKP via the IBSC.
Kindly note that, as a proactive compliance measure, the institution has requested RCGM to voluntarily withdraw the BSL-3 certification/status of the facility. In view of the same, no research activity requiring BSL-3 containment shall be initiated or continued in the facility unless certification/approval is restored by the competent authority. The facility may continue to function as a BSL-2 containment laboratory for ongoing research and molecular work.
3. Mode of Submission
All applications for IBSC review and approval shall be submitted electronically through the institutional portal (https://redcap.sjri.res.in/redcap8/) using the prescribed e-forms. Applications received through any other mode shall

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not be considered for review. Applications received beyond the notified deadline will be deferred to the next review cycle.

4. Registration and Login Credentials

Principal Investigators (PIs) shall obtain login credentials prior to submission of any proposal. For first-time users, a request shall be sent to the IBSC via email (ibsc@sjri.res.in) for registration. The IBSC Secretariat shall facilitate registration, upon which portal credentials shall be issued. These credentials shall be used for all subsequent submissions by the PI.

5. Call for Proposals

The IBSC Secretariat shall circulate a call for proposals approximately 10-15 days prior to the scheduled IBSC meeting, inviting submission of applications for review.

6. Submission Process

Applicants shall log into the portal, complete the relevant application form, and submit the duly filled form electronically. A soft copy of the completed application shall also be submitted to ibsc@sjri.res.in. The IBSC may require submission of hard copies and/or a presentation before the Committee as part of the review process, and the PI shall be accordingly notified.

For low-risk activities such as cell line experiments without genetic manipulation or studies involving human/animal blood or derivatives, the PI may initiate the process via email intimation to the IBSC with a brief study outline. Based on the submitted SOPs, the IBSC may grant email approval to commence work, which will be placed for review in the subsequent IBSC meeting; further formal submission will be required only if deemed necessary by the Committee (Refer to Table 1).

7. Review and Revision

Following review during the IBSC meeting, the Committee may suggest modifications, if required. The PI shall incorporate all recommended revisions and resubmit the updated application to the IBSC. Approval shall be considered valid only upon satisfactory incorporation of all required modifications.

Where applicable, proposals requiring RCGM/IBKP processing shall be linked with BioRRAP as mandated by DBT/RCGM. The IBSC Secretariat shall facilitate and guide such submissions. Routine IBSC applications at SJRI shall continue through the institutional submission system, and direct PI submission on BioRRAP/IBKP shall be required only when specifically advised by the IBSC.

8. Decision and Further Processing

Based on the nature of the proposed work, completeness of the application, and the category of regulated biological material involved, the IBSC may:

Grant approval and permit initiation of the research activity;

Request revision and resubmission of the application; or

Forward the application to RCGM or other relevant statutory authorities for further review and final approval.

Roles and Responsibilities of the Principal Investigator (PI)

1. The Principal Investigator (PI) shall comply with all applicable biosafety regulations, guidelines, and statutory requirements and shall be accountable to the IBSC for all research activities conducted under their supervision.
2. Based on the risk category of experiments, the PI shall inform the IBSC for Category I studies, obtain prior approval from the IBSC for Category II studies, and obtain approval from the RCGM through the IBSC for Category III and above studies before initiation.

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3. The PI shall ensure proper treatment and disposal of all biological waste and shall confirm that all organisms are adequately inactivated, destroyed, or rendered harmless prior to disposal into the environment.
4. The PI shall submit annual progress reports and a final project completion report to the IBSC as required.
5. The PI shall ensure that all laboratory personnel (technicians, technologists, students, and postdoctoral fellows) are trained and comply with biosafety requirements, including adherence to good laboratory practices, working within the assigned biosafety containment levels, and use of appropriate personal protective equipment; promptly report any health conditions that may be related to or impacted by laboratory work to the PI or Biosafety Officer (BSO) ; follow all procedures and instructions issued by the PI and BSO; and report any incidents, or non-compliance to the PI and, where necessary, to the BSO or IBSC.
6. The PI shall ensure that all incidents, including non-compliance, significant research-related accidents or illnesses, spills or exposures, are reported to the IBSC Chairperson/Member Secretary within 24 hours, and this will be reported to the RCGM by the IBSC Chairperson within 48 hours.

Table 1: Risk Classification and IBSC Approval Requirements

Risk Category	Approval requirement	GE Microorganisms	Microorganisms-BSL	GE Animals	Animals-BSL
Category I	Intimate the IBSC of study objectives and design; IBSC reviews for record/monitoring/action as needed.	Insertions of gene into RG-1 organisms with no adverse health/phenotypic/genotypic consequence; self-cloning; approved host/vector systems with donor DNA from RG-1.	BSL-1	Breeding, housing and gene-knockout experiments; GE animals transformed with RG-1 viral vector sequences; introduction of nucleic acids that do not produce infectious agents.	ABSL-1
Category II	Intimate the IBSC of study objectives and design; IBSC reviews for record/monitoring/action as needed.			Research work involving non-infected human or animal blood/blood product or derivatives*. Research work involving investigations carried out on OMICS based approaches on non-infectious FFPE tissues/ cell lines where patient's samples/ cell lines are processed for the same without any genetic modifications*.	ABSL-2
				Cell line experiments that do not involve any genetic manipulation*	ABSL-2

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	Prior authorization from the IBSC required before commencement of experiments	Work with non-approved host/vector systems or transfer of DNA from RG-2 into non-pathogenic hosts; experiments involving RG-2 microorganisms or pathogenic determinants; SDN2-type genome edits.	BSL-2	Experiments with animals infected with GE microorganisms from RG-2; studies that may affect survivorship, host range, or vector capacity but do not increase environmental fitness/virulence.	ABSL-2
Category III and above	Prior authorization from the IBSC and subsequent approval from RCGM required before commencement of experiments	Experiments on RG-2/RG-3 microorganisms involving production of toxins/allergens/antimicrobials or genetic changes that increase environmental fitness or virulence.	BSL-3/ BSL-4	Experiments with animals infected with GE RG-3 microorganisms; use of DNA encoding vertebrate toxins; studies where genetic engineering positively affects environmental fitness and virulence.	ABSL-3

*** -For studies falling under this category, the Principal Investigator (PI) may initiate the process by submitting an email request to the IBSC briefly outlining the proposed research work. Upon review of the request, the IBSC Secretariat will provide a prescribed format/template in which the PI is required to submit detailed Standard Operating Procedures (SOPs). If the submitted SOPs are determined to fall within the defined category scope or other exempt/low-risk categories as applicable, the PI will be issued an email confirmation by the IBSC permitting initiation of the experiments. Subsequently, during the next scheduled IBSC meeting, the submitted work will be placed before the committee for information and review. If, upon deliberation, the IBSC determines that the study warrants ongoing oversight or monitoring, the PI will be advised to submit a formal IBSC application for continued monitoring and approval. Otherwise, the PI may continue the work as initially permitted under the email confirmation from IBSC. For such research projects, the standard methods of handling samples should be followed to ensure biosafety of the laboratory personnel. All the laboratory personnel involved need to be immunized for Hepatitis B as applicable.**

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Table 2: Risk Group (RG) Classification

Risk Group (RG)	Description
RG 1 (no or low individual and community risk)	Microorganisms that are unlikely to cause human/animal/plant disease
RG 2 (moderate individual risk, low community risk)	Microorganisms 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
RG 3 (high individual risk, low community risk)	Microorganisms that usually cause serious or lethal human/animal/plant disease but do not ordinarily spread from one infected individual to another. Effective treatment and preventive measures are available
RG 4 (high individual and community risk)	Microorganisms that usually cause serious human or animal disease and that can be readily transmitted from one individual to another, directly or indirectly. Effective treatment and preventive measures are not usually available

Figure 1: Risk Group (RG) and Biosafety Classification

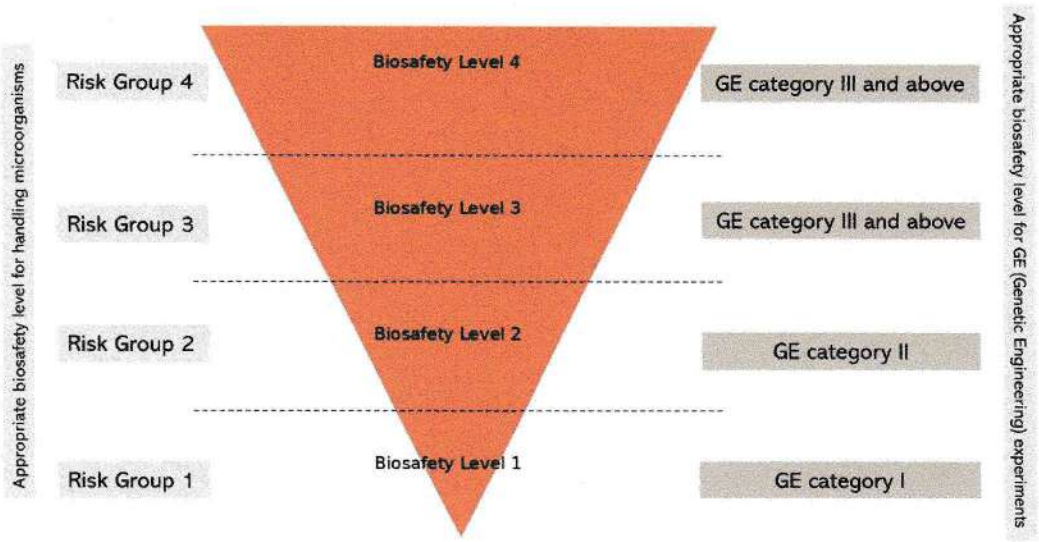

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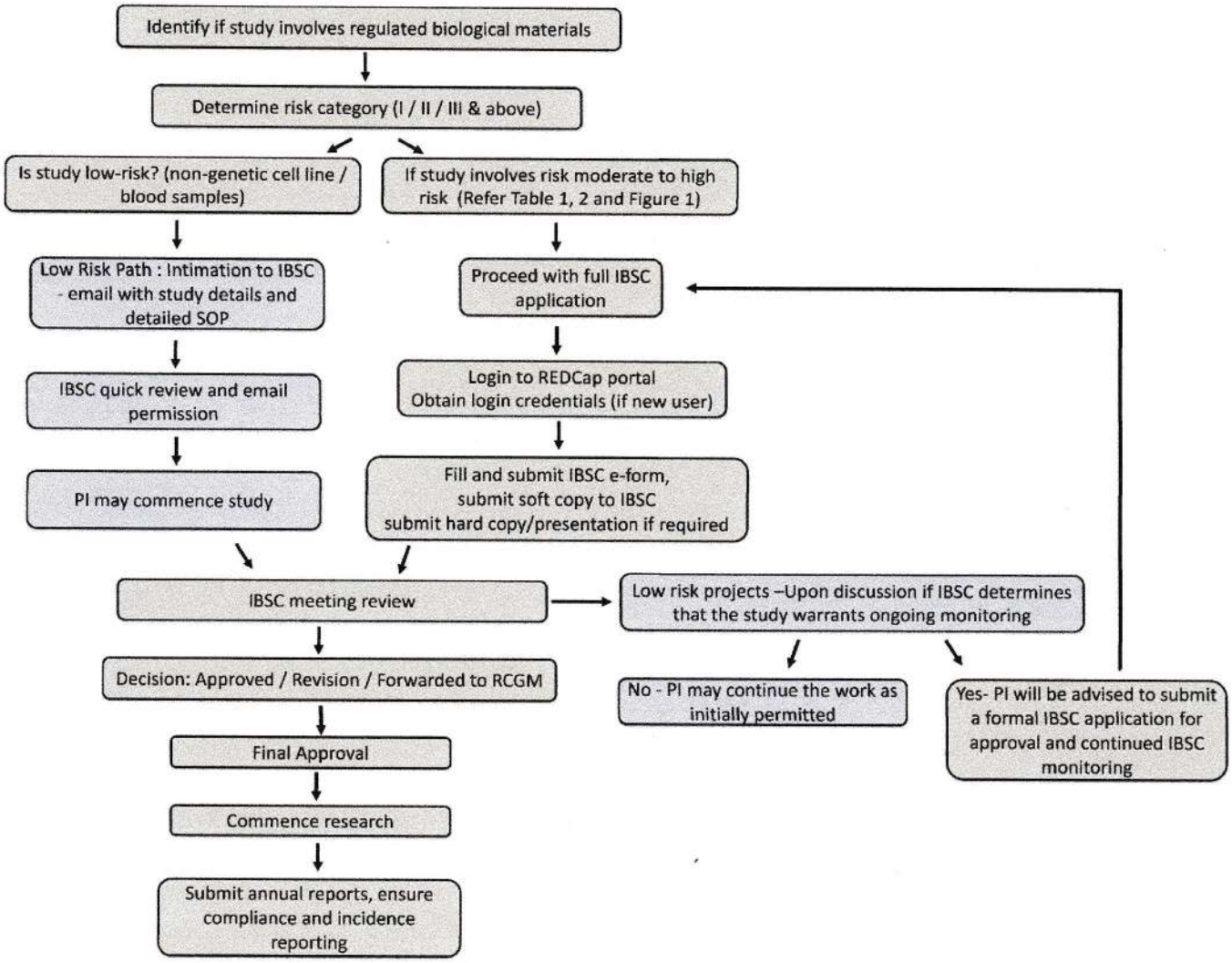
Figure 2: IBSC workflow at SJRI



Export, Import, and Transfer of Biological Materials:

All import, export, and transfer of biological materials falling under IBSC purview shall require execution of a duly signed Material Transfer Agreement (MTA) between the sender and the receiver, except in cases of import from commercial entities. IBSC approval must be obtained prior to placing any order or initiating shipment; approvals shall not be granted retrospectively if the material has already reached the port of entry and is held due to lack of clearance. The applicable forms for different use cases are provided in table 3.

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The IBSC may permit the import, export, transfer, or receipt of regulated biological materials in specified quantities for biopharmaceutical research and development and drug development activities, in accordance with the 'Revised Simplified Procedure/Guidelines on Import, Export and Exchange of Regulated Items, 2020' (Download here).
In cases where export of biological materials falls under the Special Chemicals, Organisms, Materials, Equipment and Technologies (SCOMET) category, the applicant shall obtain necessary approvals from the IBSC/RCGM and subsequently apply to the Directorate General of Foreign Trade (DGFT), Ministry of Commerce (www.dgft.gov.in).
For import of genetically modified (GM) plants and planting materials, applications shall be routed through the Director, National Bureau of Plant Genetic Resources (NBPGR), Indian Council of Agricultural Research (ICAR), based on the authorization issued by the RCGM Secretariat.

Table 3: LIST OF FORMS/PERFORMA AVAILABLE ON IBKP

Section	Form No.	Description
IMPORT, EXPORT, TRANSFER AND RECEIVE OF REGULATED MATERIAL FORM	FORM B1	Application to RCGM for Import of HMOs, GMOs/LMOs and Product(S) Thereof for Research & Development Purpose
	FORM B3	Application to RCGM for Export of HMOs/GMOs/LMOs & Product(S) Thereof for Research & Development Purpose
	FORM B5	Application to RCGM for Receiving HMOs, GMOs/LMOs & Product(S) Thereof For Research & Development Purpose within India
	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 C	For non-infectious biological material: Introduced later by DBT/RCGM to simplify import/export of non-infectious samples (human, animal, plant origin, UN3373 Class B)
ACTIVITIES INVOLVING RESEARCH, PRODUCTION, PRECLINICAL STUDIES OF GMOS IN HEALTHCARE/ACTIVITIES INVOLVING RESEARCH, PRODUCTION, PRECLINICAL AND OTHER STUDIES	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 C3a	Application to RCGM to Conduct Preclinical and/or Safety Studies of Similar Biologic Developed Using GMOs/ LMOs for Healthcare and Industrial Use
	FORM C3b	Application to RCGM to Conduct Preclinical and/or Safety Studies of New DNA Product Developed Using GMOs/

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		LMOs
	FORM C5a	Submission of Report of Preclinical or Other Safety Studies of Similar Biologic Developed Using GMOs/ LMOs
	FORM C5b	Submission of Report of Preclinical or Other Safety Studies of New rDNA Product Developed Using Genetically Modified Organisms (GMOs)/ Living Modified
	FORM F3	Submission of Report on Restricted Release Research Study/(ies)/ Trial(S) Of Genetically Engineered (GE) Arthropods for Agricultural, Healthcare and Environmental Use
ACTIVITIES INVOLVING RESEARCH AND SAFETY STUDIES OF GE PLANTS	FORM D1	Information to RCGM to Carry Out Research and Development Involving Hazardous Microorganisms (HMOs), Genetically Modified Organisms (GMOs)/ Living Modified Organisms (LMOs) For Agricultural And Environmental Application
	FORM D3 Event Selection	Application to Undertake Confined Field Trial and To Undertake Safety Studies of Genetically Engineered Crops/ Plants for Agricultural and Environmental Use
	FORM D3 BRL-1	Application to Undertake Confined Field Trial and To Undertake Safety Studies of Genetically Engineered Crops/ Plants for Agricultural and Environmental Use
	FORM D3 BRL-2	Application to Undertake Confined Field Trial and To Undertake Safety Studies of Genetically Engineered Crops/ Plants for Agricultural and Environmental Use
	FORM D3 Other	Application to Undertake Confined Field Trial and To Undertake Safety Studies of Genetically Engineered Crops/ Plants for Agricultural and Environmental Use
	FORM D7	Submission of Report of Safety Studies of Genetically Engineered (GE) Crops/Plants for Agricultural and Environmental Use
	FORM E3	Submission of Report of Safety Studies of Hazardous Microorganisms (HMOs), Genetically Modified Organisms (GMOs)/ Living Modified Organisms (LMOs) Other Than GE Crops/ Plants for Agricultural and Environmental Use
	FORM F3	Submission of Report on Restricted Release Research Study(s)/ Trial(s) of Genetically Engineered (GE) Arthropods for Agricultural, Healthcare and Environmental Use

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Institutional Biosafety Committee

LOW-RISK STUDY SOP SUBMISSION FORM

For non-GMO studies involving human/animal blood, blood products, derivatives, non-infectious FFPE tissues, OMICS-based sample processing, and cell line experiments without genetic manipulation

A.Preliminary category:

☐ Human blood / blood product / derivative	☐ Animal blood / blood product / derivative
☐ Non-infectious FFPE tissue	☐ OMICS-based sample processing
☐ Cell line experiment without genetic manipulation	☐ Other low-risk category: _____

B. Principal Investigator Details:

Name of Principal Investigator	
Designation	
Department / Unit	
Institution	
Email ID	
Mobile / Phone number	
Co-investigator/s, if any	
Name/s of student/s / research staff involved	

C. Study Details:

Title of proposed work	
Type of submission	☐ New ☐ Ongoing ☐ Amendment ☐ Continuation of previously permitted low-risk work
Study category	☐ Dissertation/thesis ☐ Intramural project ☐ Extramural funded project ☐ Departmental study ☐ Diagnostic/method validation-related work ☐ Other
Funding source, if applicable	
Proposed duration	From: _____ To: _____

Brief purpose of the study with detailed SOP (less than 1000 words):

D. Type of Biological Material to be Used

1. Human-derived material

☐ Whole blood	☐ Serum	☐ Plasma
☐ Buffy coat	☐ PBMCs	☐ Saliva
☐ Urine	☐ Stool	☐ Tissue biopsy
☐ FFPE tissue	☐ Fresh tissue	☐ Bone marrow
☐ Cord blood	☐ Other: _____	

2. Animal-derived material

☐ Animal blood	☐ Serum / plasma
☐ Tissue	☐ Cell / tissue lysate
☐ Other: _____	

3. Cell lines

☐ Established human cell line	☐ Animal cell line
☐ Primary cell line	☐ Cancer cell line
☐ Commercially procured cell line	☐ Cell line obtained from collaborator
☐ Other: _____	

Name of cell line/s, if applicable	

4. Sample status

☐ Non-infectious	☐ De-identified / anonymized
☐ Archived sample	☐ Prospectively collected sample
☐ Commercially procured material	☐ Sample from collaborator
☐ Infectious status unknown	☐ Other: _____

E. Source and Documentation of Material (If export/import involved)

Source of material	☐ Patient/participant ☐ Healthy volunteer ☐ Clinical laboratory ☐ Blood bank ☐ Biobank/repository ☐ Commercial supplier ☐ Collaborating institution ☐ Existing stored samples ☐ Other
Approximate number of samples / cell lines	
Approximate volume / quantity per sample	
Will samples be identifiable?	☐ Yes ☐ No ☐ Not applicable
Will clinical data be linked to samples?	☐ Yes ☐ No ☐ Not applicable
IEC approval / exemption status	☐ Approved ☐ Exemption obtained ☐ Submitted and pending ☐ Not applicable ☐ To be obtained
IEC approval / exemption number, if available	
Material Transfer Agreement applicable?	☐ Yes ☐ No ☐ Not applicable
Is import / export / inter-institutional transfer involved?	☐ Yes ☐ No. If yes, provide details:

F. Confirmation of Low-Risk Eligibility

Question	Yes	No	Remarks
Does the study involve genetic modification?	☐	☐	
Does the study involve recombinant DNA work?	☐	☐	
Does the study involve genome editing?	☐	☐	
Does the study involve viral vectors?	☐	☐	
Does the study involve transformation/transfection/transduction?	☐	☐	
Does the study involve culture or propagation of microorganisms?	☐	☐	
Does the study involve known infectious samples?	☐	☐	
Does the study involve BSL-3 organisms or BSL-3 containment?	☐	☐	
Does the study involve creation of new cell lines?	☐	☐	
Does the study involve only sample processing/analysis without propagation?	☐	☐	
Does the study involve cell line work without genetic manipulation?	☐	☐	
Does the study involve OMICS analysis only?	☐	☐	
Does the study involve FFPE/non-infectious archived tissue?	☐	☐	

Note: If "Yes" is selected for genetic modification, recombinant DNA work, genome editing, viral vectors, known infectious samples or BSL-3 containment, this form may not be sufficient and a full IBSC application may be required.

Will live cells be handled?	☐ Yes ☐ No
Will samples/cells be stored after completion of the study?	☐ Yes ☐ No. If yes, mention duration and storage location:
Will any residual biological material be transferred to another laboratory/institution?	☐ Yes ☐ No. If yes, provide details:

G. Biosafety Practices and PPE

Will all samples be handled as potentially infectious unless documented otherwise?	☐ Yes ☐ No ☐ Not applicable
PPE to be used	☐ Laboratory coat/gown ☐ Gloves ☐ Double gloves ☐ Mask ☐ N95 respirator ☐ Eye protection/face shield ☐ Shoe cover ☐ Other
Will aerosol-generating procedures be performed?	☐ Yes ☐ No. If yes, mention precautions:
Will sharps be used?	☐ Yes ☐ No. If yes, mention disposal method:
Have personnel received relevant biosafety training?	☐ Yes ☐ No ☐ Planned
Hepatitis B immunization status for personnel handling blood/blood products/patient samples	☐ Completed ☐ In progress ☐ Not applicable ☐ As per institutional occupational health/Infection Control Committee protocol

H. PI Declaration

I declare that the information provided above and in the enclosed SOPs is true and accurate to the best of my knowledge.

I confirm that the proposed work does not involve genetic modification, recombinant DNA work, genome editing, viral vectors, known infectious samples, BSL-3 organisms, or any activity requiring BSL-3 containment.

The work will be initiated only after written/email confirmation from the IBSC Secretariat and will be conducted strictly as per submitted SOPs and institutional biosafety practices.

Any change in scope, biological material, procedure, personnel, location, storage, transfer, or risk category will be submitted to the IBSC for prior review.

All biological waste will be appropriately decontaminated and disposed of as per institutional biomedical waste procedures.

All incidents, spills, exposures, accidents or non-compliance will be reported to the IBSC as per institutional policy.

Personnel handling human blood, blood products, patient-derived samples or potentially infectious biological materials shall follow applicable occupational health requirements, including Hepatitis B immunization where required.

Name of PI	
Signature	
Date	