

**Environmental Health Risk Management Plan (EHRMP)**

**National Institute of Immunology (NII)**

Proposal entitled: **A novel vaccine evaluation platform to support SARS-CoV-2 vaccine development in resource-limiting settings**

I. Brief description of the proposed activity:

This project has been designed to provide the well-characterized animal model for evaluating the long-term efficacy of vaccines that are in early phase of development. The aim of this project is to develop the animal model based vaccine evaluation platform that would test the immunogenicity, quality and stability of protective immune response induced by any vaccine candidate. By providing a vaccine evaluation model that can be handled in BSL-2 facility the outcome from this project would be beneficial in speeding up the vaccine evaluation in early phase with easily identifiable targets to evaluate the efficacy of a candidate under development. Following activities are proposed under this project:

1. Characterization of Animal model for evaluation of SARS-CoV-2 vaccine.
2. Development of in vitro and in vivo vaccine evaluation assays using the SARS-CoV-2 pseudovirus.
3. Development of synthetic Peptide-MHCII T-cell tetramer for evaluating vaccine long-term efficacy.

II. List of environments related regulatory clearances required for the activity.

No such clearance is required for this project. In addition to the systematic waste disposal procedure, NII has institutional committee that ensures implementation of standard bio-safety guidelines. NII also complied with the government emergency regulations with fire exit signs, necessary equipment's to control fire and periodic trainings of the staff at work place.

**Institutional Arrangement**

Area of Risk		Yes	No	Details	Proposed Plan
1.	Is there a designated full-time staff for Environment Health and Safety (EHS) issues?		√	No exactly with such designation, but a Biomedical office from institute take care of such responsibility	The proposed project elements will be covered by any committees/ agencies within NII.
2.	Does the EHS staff handle the following?			Biomedical officer from NII is also member of IBSC. Thus, consent regulatory clearances as well as record keeping of accidents.	Necessary and mandatory approvals will be taken as and when required.
	Occupational Health and Safety	√			
	Waste Management	√			
	List of consents and regulatory clearances	√			
	Record keeping of accidents and procedures	√			
	EHS trainings for staff		√		
	Environment Management Framework compliance for Innovate in India Project		√		Environment Management Framework compliance for Innovate in India Project will be followed

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3.	Is there a reporting structure in place regarding EHS issues?		√	It is taken care by Institutional Biosafety Committee.	We will follow the plan with a proper structure in place.
4.	Are regular EHS trainings provided to staff?		√	IBSC gives periodic training.	This will be regularly followed by ensuring adherence to the requirements.
5.	Institutional Bio-Safety Committee (IBSC)	√		Review and approve the projects related to biosafety with at least 3 meetings in a year	Now, we are switching completely to digital one through IBKP portal of DBT with periodic review. Research Unit will comply with Bio- Safety Committee requirement throughout the project.
6.	Ethics Committee (EC)	√		Review and approve the projects related to research involving human subjects with at least one meeting in a year	The Ethics Committee will be scheduling meetings regularly depending on the requirement. During the meeting, the members will review the new project proposals and also review the progress of the ongoing projects.  They will review the ethical and the informed consent related issues pertaining to research project.

**General Occupational Health and Safety**

	Area of Risk	Yes	No	Details	Proposed Plan
7.	Are there Standard Operating Procedures for accidents, hazards, and other emergencies (chemical spills, heat hazards, fire hazards, radioactive hazards etc.)?	√		Procedures for handling corrosive chemicals, chemical spill as well as fire extinguisher are in place.	A structured system is in place. Display of Procedures at prominent places in the site will be ensured.
8.	Are the following in place?			All scientific and technical staff uses Lab aprons. Eye wash and Shower stations are available in nearest washroom.	A structured system is in place. Proper equipment will be in place and stock will be maintained as per the Institute's guidelines for Environment Health and Safety (EHS).
	Chemical spill kits	√			
	Eye wash	√			
	Shower stations	√			
	First Aid Kit	√			
	Fire Extinguishers	√			
	Register of accidents and injuries	√			

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9.	Are proper signage and storage system in place?		√	Yes, proper system is in place.	Research Unit will comply with organization policy and maintain a proper regulation of these requisites.  These would be regularly updated/ replaced while carrying out maintenance.
	Display of Material Safety Data Sheet (MSDS) where relevant		√		
	Display of emergency numbers and procedures (Person to Contact, Doctor, Ambulance, Fire Emergency, Police) displayed in all critical places	√			
	Signage across the facility (labs, storage, hazardous areas, etc.)	√			
	Are flammable materials appropriately stored to prevent fire hazards?	√			
10.	Are smoke detectors, fire alarms, automatic safety/shut off systems, overflow preventors, etc. in place and regularly maintained?	√		Yes, automatic systems are in place.	The work department follow the SOP.  These would be regularly maintained.
11.	Are there control measures for VOC, air emissions, high operating temperatures, pathogens/vectors etc. in place?	√		We have chemical hoods and Biosafety cabinets to handle VOC and air emissions and Pathogens	The SOP will be followed.
12.	Are regular mock drills conducted for emergency preparedness and safety?	√		Setup has mock drills for fire safety once in year	The work department follow the SOP.
13.	Are staff provided with OHS training?	√		Students/regular staff during lab courses were taught about safety procedures	Temporary Staff/ visitor joining the lab will have training at the time of joining
<b>Biomedical Waste (BMW)</b>					
	<b>Area of Risk</b>	<b>Yes</b>	<b>No</b>	<b>Details</b>	<b>Proposed Plan</b>
14.	Is there generation of biomedical waste (as described in Bio-Medical Waste Management Rules, 2016) in the grantee?	√		As part of research following biomedical waste is generated.	The institutional biomedical waste management systems in place.  BMW generated will be treated adhering to Bio-Medical Waste Management Rules, 2016.

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15.	Is there trained staff to handle biomedical waste in the grantee?	√		Yes, staff working in lab is trained to handle and segregate.	Follow the institutional policy.
16.	Has the grantee obtained authorization from State Pollution Control Board /Pollution Control Committee?		√	The institutional structure is in place.	The institutional structure is in place and followed.  Necessary approvals and authorizations will be obtained from the SPCB as and when required
17.	Is the biomedical waste segregated at point of generation in the facility and stored in suitable containers?	√		Yes, biomedical waste segregated at point of generation in the facility and stored in suitable containers	This is an ongoing process which will be followed throughout the Project.
18.	Is the bar code system for the segregated waste in place?		√	No barcode system.	The institutional biomedical waste management systems in place.  Bar coding will be done as per BMW rules
19.	Is the biomedical waste being sent to an <b>authorized</b> common BMW facility?	√		The institutional biomedical waste management systems in place.	The institutional biomedical waste management systems in place.
20.	Does the grantee have an in-house BMW treatment facility?		√		The institutional biomedical waste management systems in place.
	Is the treatment facility own (individual)?		√		
	Is the treatment facility a shared facility in an industrial park?		√		
21.	Are lab waste, microbiological waste and chemical liquid waste pre-treated before storing and sending to treatment facilities according to guidelines prescribed in BWM, 2016 regulations?	√		Autoclaving	Compliance with the institutional biomedical waste management systems.

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22.	Is the liquid waste checked for active cells before sending to treatment plant?		√		All the liquid waste discarded with Sodium hypochlorite treatment.
23.	Are necessary waste pre-treatment equipment in place?	√		Autoclaves	Pre-Treatment will be done by decontamination by our staff regularly.
	Do the equipment adhere to prescribed norms by State Pollution Control Board (SPCB)?	√			
24.	Are chlorinated plastic gloves and bags phased out in the grantee?		√		Decomposed in regular waste after sodium hypochlorite treatment.
25.	Are grantee's personnel involved in handling BMW provided with regular training?	√		Institute has independent staff to handle biomedical waste management	Institute has independent staff to handle biomedical waste management
26.	Are medical examination provided to personnel involved in BMW waste handling and are they provided with relevant immunization like Hepatitis B and Tetanus?	√		The institutional biomedical waste management systems is in place.	The institutional biomedical waste management systems will be followed.
27.	Is a daily register for biomedical waste maintained including accident reporting record?	√		The institutional biomedical waste management systems is in place.	
28.	Are annual reports on BWM submitted to SPCB as per required form (see Bio-Medical Waste Rules 2016)?		√	The institutional policy for biomedical waste management systems is in place.	The institutional policy for biomedical waste management systems will be followed.
<b>Hazardous Waste (HW)</b>					
	<b>Area of Risk</b>	<b>Yes</b>	<b>No</b>	<b>Details</b>	<b>Proposed Plan</b>
29.	Is there generation of hazardous waste (as per Hazardous Waste Rules, 2016) in the grantee?		√		If any hazardous waste is generated as per rules it will be handled and disposed.
30.	Is there trained staff in the facility to identify and handle hazardous waste?	√		IBSC handles it.	Follow the IBSC guideline.

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31.	Does the grantee have authorization from SPCB for hazardous waste?		√		Necessary Authorizations will be taken if required.
32.	Is there a secure location for storage of HW with proper signage?		√		We will arrange proper storage facilities when required
	Are hazardous waste stored for more than 90 days in the grantee's premises?		√		
33.	Is the hazardous being send to an <b>authorized</b> disposal facility or user?		√		Hazardous waste will be sent to authorized recycler if generated
	Is the disposal facility in house?		√		
	Is the disposal facility external/outsourced?		√		
34.	Is a register maintained on production and treatment, and a manifest system followed for transport of hazardous waste from the grantee to treatment facility?		√		We will maintain the register when required

**E-Waste and Batteries**

	Area of Risk	Yes	No	Details	Proposed Plan
35.	Does the grantee generate e-waste, produce or manufacture electrical and electronic equipment?		√	No substantial electrical waste is generated in the lab	Procedures will be followed as per the guidelines.
36.	Has the grantee obtained SPCB authorization on e-waste?		√	No substantial electrical waste is generated in the lab	Necessary Authorizations will be taken if required.
37.	Does the grantee channelize the e-waste to <b>authorized</b> recycling or disposal facility?		√	No substantial electrical waste is generated in the lab	Appropriate steps will be taken and necessary authorizations will be taken if required.
38.	Does the manufacturing grantee have Extended Producer Responsibility system and EPR-authorization in place?		√	No substantial electrical waste is generated in the lab	
39.	Does the grantee practice reduction in the usage of hazardous substances in the		√	No substantial electrical waste is generated in the lab	

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	manufacture of electrical and electronic equipment and its parts?				
40.	Does the grantee provide detailed information on the constituents of the equipment and their components/spares and declaration of conformation to Reduction in Hazardous Substances in the product user documentation?		√	No substantial electrical waste is generated in the lab	
41.	Does the grantee maintain a record of collection, storage, sale and transport of e-waste?		√	No substantial electrical waste is generated in the lab	
42.	Does the grantee submit annual reports on e-waste to SPCB?		√	No substantial electrical waste is generated in the lab	
43.	Is there accident reporting and records in place?		√	No substantial electrical waste is generated in the lab	
44.	Are PPEs available to staff?		√	No substantial electrical waste is generated in the lab	The stock status of PPE will be regularly monitored and procurement will be done in time to avoid any situation of stock out.
45.	Is the grantee involved in manufacture of batteries?		√	No substantial electrical waste is generated in the lab	
46.	Does the grantee generate battery waste?		√	No substantial electrical waste is generated in the lab	
47.	Does the grantee deposit the battery waste to <b>registered</b> recycler/dealer/manufacturer/r econditioner/collection center?		√	No substantial electrical waste is generated in the lab	
48.	In case of manufacturing, does the grantee comply to Battery Management Rules 2000 and ensure collection of old batteries?		√	No substantial electrical waste is generated in the lab	
<b>Community Health and Safety and risk mitigation</b>					
		<b>Yes</b>	<b>No</b>	<b>Details</b>	<b>Proposed Plan</b>
49.	Safety Transportation Management System (for transport of hazardous material)	√		Only autoclaved material is disposed off.	Will follow the safety transport management system if required

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50.	Emergency preparedness and participation of local authorities and potentially affected communities		√		Will develop the emergency preparedness plan if required
<b>Other</b>					
	<b>Area of Risk</b>	<b>Yes</b>	<b>No</b>	<b>Details</b>	<b>Proposed Plan</b>
51.	Does the grantee use any radioactive materials (isotopes tracers, radiation equipment, etc)?		√		we don't use radioactive material
	Does the grantee have appropriate radioactive material and waste storage and disposal system in place?		√		If we use, then we will arrange for proper storage and disposal
	Are radioactive warning signs in place?		√		Will be implemented if required
52.	Is the lab/room air regularly checked for microbial contamination?		√	No microbial work is done in the lab	Will be implemented if required
53	Are there any odor control measures in place?		√		Periodic checks will be done preventive measures will be taken if required
54.	Are fume hoods and exhausts regularly checked and maintained?	√		Exhaust installed and checked in dedicated area.	Periodic checks will be done
55.	Does the grantee use DG set > 15 KVA?		√	We use electricity supplied through state electricity distributors	If DG sets are used then emissions will be regularly monitored as per CPCB norms if procured
	Does the grantee have consent for DG > 15 KVA?		√		
	Are emissions from boilers and DG sets regularly monitored to be within the prescribed norms?		√		
56.	Does the grantee have proper disposal process for solid and plastic waste in compliance to Solid Waste Management Rules, 2016 and Plastic Waste Management Rules, 2016?		√	Describe: It will be ensured that segregation rules are followed	This will be maintained and monitored



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57.	Is wastewater treated separately by the grantee? (Liquid waste from laboratory, chemicals, fluids, solvents, medium and cultures, coolants, etc.)	√		Wastewater treatment plant exist in the institute.	
	Are there sludge management and cut off drains in place for wastewater?	√			
58.	Are necessary provisions for noise cancellation in place?	√		No noise is generated in the institute.	Preventive measures will be taken for reducing noise levels if generated
59.	Are there any settlements, water bodies, cultivated land, or any other eco-sensitive areas near the grantee's premises?		√	No	
60.	Are there any buffers, fire vehicle routes in the grantee's premises?	√		Fire vehicle routes are available	
<b>COVID Precautions &amp; Guidelines Implementation</b>					
61.	Guidelines of CPCB/SPCB/GoI for Handling, Treatment, and Disposal of COVID Waste Generated is whether being followed?	√		Training provided on COVID to all the staff.	Masks and gloves and PPE are used.
62.	SOP on preventive measures to contain spread of COVID-19 issued by ICMR/GoI from time to time is whether being followed?	√		All the necessary procedures are followed	Regular sanitization in the premises, Thermal screening is in place.

**Notwithstanding the above other risk (relevant to the project activities) that will be identified in the course shall be addressed as per standard mitigation monitoring parameters and manner of records keeping shall be in accordance to the recommendations of the project monitoring committee on subject experts engaged by BIRAC.**