

## Environmental Health Risk Management Plan (EHRMP)

### ICMR – National Institute of Epidemiology

Proposal entitled “Establishment of surveillance system in a rural population cohort for describing epidemiology of dengue infection towards setting up of field-based clinical trial site in model rural health research unit in Tirunelveli, Tamil Nadu

#### 1. Institutional Arrangements

- (i) Brief description of the proposed activity- This is an epidemiological project where in the incidence and seroprevalence of dengue and chikungunya in a sample population is being assessed. There is no intervention being given, however some blood samples will be collected for doing serological tests for the study.
- (ii) List of environments related regulatory clearances required for the activity- This project will need some of the regulatory clearances like the state pollution control board and biomedical waste management clearances (which already exist with the medical college we are partnering with). These clearances are keeping in mind the collection of biological specimens (blood) and the waste generated during this process.

<b>Institutional Arrangement</b>					
		Yes	No	Details	Proposed Plan
1.	Is there a designated full-time staff for Environment Health and Safety (EHS) issues?	Yes		Currently, the center has formed a bio-safety committee that looks after the environmental, Occupational health and bio-safety related issues.	The center will constitute a separate EHS committee to address the Environment Health and Safety measures in the centre.
2.	Does the EHS staff handle the following?			Currently the generated bio-waste is included in the bio-waste generated at the Kallur PHC and is handed over to the designated bio-waste management agency.	The EHS staff appointed by the committee will look after the issues and the activity will be governed and reviewed as per Institute’s guidelines for Environment Health and Safety (EHS).
	Occupational Health and Safety	Yes			
	Waste Management	Yes			
	List of consents and regulatory clearances	Yes			
	Record keeping of accidents and procedures	Yes			
	EHS trainings for staff	Yes			
	Environment Management Framework compliance for Innovate in India Project	Yes		This project will follow the Environment Management Framework by NBM, BIRAC	

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3.	Is there a reporting structure in place regarding EHS issues?	Yes		Frequency: Currently, training on environmental and occupational health (Bio medical waste management, bio-safety, preventing exposure to hazards, fire related accidents etc.) are being carried out in the center. Such trainings are done half yearly.	Under this project, all the project staff and research team will undergo the EHS training. Afterwards refresher training will be provided on every six months.
4.	Are regular EHS trainings provided to staff?	Yes		Frequency: Currently, training on environmental and occupational health (Bio medical waste management, bio-safety, preventing exposure to hazards, fire related accidents etc.) are being carried out in the center. Such trainings are done half yearly.	Under this project, all the project staff and research team will undergo the EHS training. Afterwards refresher training will be provided on every six months.
5.	Institutional Bio-Safety Committee (IBSC)		No	Currently it is not constituted.	Will be constituted within 3 months.
6.	Ethics Committee (EC)	Yes		ICMR-NIE has a DCGI approved ethics committee. The ethics committee consists of reprehensive external members/experts from various domains such as medical, social welfare, woman representative, social activist, Legal person,	Generally, the institution ethics committee meets every month or once in two months depending on the number of project proposals for review. During the meeting, the members review the new project proposals and also review the progress of

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				SC/ST representative etc. The senior medical expert being the chairperson of the ethics committee.	the ongoing projects. They review the ethical, scientific and the informed consent related issues pertaining to research project.
<b>General Occupational Health and Safety</b>					
7.	Are there Standard Operating Procedures for accidents, hazards, and other emergencies (chemical spills, heat hazards, and fire hazards, etc.)?	Yes		ICMR-NIE has an institutional bio-safety committee that takes care of the occupational hazards following the guidelines. All laboratory staff under the monitoring of the principal-investigators strictly use the personal protective measures	Display of Procedures in prominent places in the sites will be done.
8.	Are the following in place?			All the laboratories have adequate chemical spill kits, eye wash facilities, shower stations, first aid kit, fire extinguishers as per the protocol.	Appropriate SOPs are in place and will be followed to deal with such emergencies.
	Chemical spill kits	Yes			
	Eye wash	Yes			
	Shower stations	Yes			
	First Aid Kit	Yes			
	Fire Extinguishers	Yes			
9.	Are proper signage and storage system in place?	Yes		Signage and storage system to keep samples, display of material safety data sheet in appropriate places, contingency plan with emergency contact numbers of concern officials are available.	These would be regularly updated/replaced and reviewed.
	Display of Material Safety Data Sheet (MSDS) where relevant	Yes			
	Display of emergency numbers and procedures (Person to Contact, Doctor, Ambulance, Fire Emergency, Police) displayed in all critical places	Yes			
	Signage across the facility (labs, storage, hazardous areas, etc.)	Yes			
	Are flammable materials appropriately stored to prevent fire hazards?	Yes			

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10.	Are smoke detectors, fire alarms, automatic safety/shutoff systems, overflow preventors, etc. in place and regularly maintained?	No		Presently smoke detectors are not present	Smoke detectors and alarms will be installed before the start of the project
11.	Are there control measures for VOC, air emissions, high operating temperatures, pathogens/vectors etc. in place?	No		Presently these measures are not established	These measures will be established during the course of the study.
12.	Are regular mock drills conducted for emergency preparedness and safety?	Yes		Frequency (type wise): Quarterly	
13.	Are staff provided with OHS training?	Yes		Describe: The staffs will be trained once they are recruited under the project.	
<b>Biomedical Waste (BMW)</b>					
14.	Is there generation of biomedical waste (as described in Bio-Medical Waste Management Rules, 2016) in the grantee?	Yes		If Yes, provide a list of biomedical waste produced in the facility- The following categories of Biomedical Wastes are produced in MRHRU Microbiological waste, blood products, sharps, liquid wastes and solid waste	All the staff will be trained on Bio-Medical waste management and all of them shall be responsible for managing the wastes (collection, segregation and handing over to out sourced agency. The out sourced agency will take care of its transportation, treatment and final disposal.
15.	Is there trained staff to handle biomedical waste in the grantee?	Yes		All the staffs are trained for bio-medical waste management. ICMR-NIE conducts such training regularly every 6 monthly. The PI, Co-PI and other core team members are trainers.	It will be a continual ongoing process. The trainers are In-house institutional scientists and few trainers from SPCB.
16.	Has the grantee obtained authorization from State Pollution Control Board		No		Tamil Nadu State Pollution control

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	/Pollution Control Committee?				board certificate will be obtained by 31 May 2020.	
17.	Is the biomedical waste segregated at point of generation in the facility and stored in suitable containers?	Yes		Yellow	Yes	Will be treated as per Bio-Medical Waste Management (Amendment) Rules, 2018
				Red	Yes	
				White	Yes	
				Blue	Yes	
18.	Is the bar code system for the segregated waste in place?		No	Action will be taken to install the bar code system for waste segregation.	Will follow the process laid down under Bio-Medical Waste Management (Amendment) Rules, 2018	
19.	Is the biomedical waste being sent to an authorized common BMW facility?	Yes		Name and address of CBMWF: Aseptic Systems Co.  Distance from facility: 25 km  Frequency and Mode of transport: Daily/ By road  Who transports? Personnel from Aseptic systems transport the BMW		
20.	Does the grantee have an in-house BMW treatment facility?		No	Reason: No proper space is available  Authorization: Not available  Distance of nearest CBWM from facility: 20 kms	Will be routinely done.	
	Is the treatment facility own (individual)?		NA			
	Is the treatment facility a shared facility in		NA			

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	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?	Yes		Types of treatment: Decontaminated with sodium hypochlorite solution, proper washing and rinsing and Autoclaving for sterilization	Compliance calendar shall be maintained.
22.	Is the liquid waste checked for active cells before sending to treatment plant?		No		Appropriate action will be taken to check the liquid wastes before its treatment/management. One microbiologist will be trained for the same.
23.	Are necessary waste pre-treatment equipment in place?	Yes		List of equipment (autoclaves, shredders, incinerators, etc.): Autoclaves and shredders.  Details of waste pre-treatment: Hypochlorite solution (as per guideline)	
	Do the equipment adhere to prescribed norms by State Pollution Control Board (SPCB)?	Yes			
24.	Are chlorinated plastic gloves and bags phased out in the grantee?	Yes			
25.	Are grantee's personnel involved in handling BMW provided with regular training?	Yes		Frequency: Half yearly  Trainer: External & Internal	
26.	Are medical examination provided to personnel involved in BMW waste handling and are they provided with relevant immunization like Hepatitis B and Tetanus?		No		Annual Health Checkup and HBV and Tetanus immunization will be provided to concerned personnel prior to

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					study initiation.
27.	Is a daily register for biomedical waste maintained including accident reporting record?	Yes		A register for biomedical waste is maintained in addition to the accident reporting register	This practice would be followed and checked periodically.
28.	Are annual reports on BWM submitted to SPCB as per required form (see Bio-Medical Waste Rules 2016)?		No	May be planned to do the same in future	Annual report will be submitted to SPCB as per the biomedical waste management rules.
<b>Hazardous Waste (HW)</b>					
29.	Is there generation of hazardous waste (as per Hazardous Waste Rules, 2016) in the grantee?	Yes		If Yes, provide a list of hazardous waste produced in the facility Chemical- Reagents, Disinfectants Biological- Microorganism contaminated wastes Flammable- Used oil from DG set If No, provide a list of all waste produced in the facility.	All these wastes will be managed according to the Bio medical Waste management guideline of Tamil Nadu state.
30.	Is there trained staff in the facility to identify and handle hazardous waste?		No	One staff will be trained for the same.	Based on the requirement a Consultant will be hired on need basis.
<b>E-Waste and Batteries</b>					
31.	Does the grantee generate e-waste, produce or manufacture electrical and electronic equipment?	Yes		Computer sets, Key boards, Tablets, mobile phones	The e-wastes generated in the centre will be stored within the campus of the centre.
32.	Has the grantee obtained SPCB authorization on e-Waste?		No	SPCB approval, authorization approval from SPCB will be	Necessary approvals will be taken.

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				obtained.	
33.	Does the grantee channelize the e-waste to <b>authorized</b> recycling or disposal facility?		No	Name and address of disposal facility/ recycler:  In house or outsourced Facility:	For disposal of e-waste, an appropriate authorized agency empanel by Govt. of Tamil Nadu will be outsourced. Appropriate agency will be identified before initiation of the project.
34.	Does the grantee submit annual reports on e-waste to SPCB?		No	Equipment condemnation register	NIE will fulfill the requisite essential on attaining approvals from the relevant authorities.
35.	Is there accident reporting and records in place?	Yes		Records are in place to document and report any accidents within the laboratory. There is a contingency plan for the laboratory available. In the event of any such accident, the bio-safety committee members along with the concern persons are immediately informed.	The bio-safety committee members along with Director of the institution and the laboratory In-charge will take appropriate action to prevent and manage any accidents.
36.	Are PPEs available to staff?	Yes		Necessary PPEs are available in stock for the laboratory staff adequately	The stock status of PPE will be regularly monitored and procurement will be done in time to avoid any situation of stock out.
37.	Is the grantee involved in manufacture of batteries?		No		
38.	Does the grantee generate battery waste?	Yes		The battery waste	The e-wastes will be



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				from the inverter, tablets will be generated	collected and isolated within the premises of center for condemnation. An appropriate agency will be outsourced for disposal of e-wastes.
<b>Community Health and Safety and risk mitigation</b>					
39.	Safety Transportation Management System (for transport Of hazardous material)	Yes		Outsourced to agency for transportation and final disposal of the wastes.	Will follow the same for the project activities along with ensuring the contract with the outsourced agency is renewed on time.
40.	Emergency preparedness and participation of local authorities and potentially affected communities	Yes		An emergency mitigation committee (Rapid task force) consisting of core team members and local authorities from health system is constituted to ensure emergency mitigation. This will be led by the PI/Co-PI as the coordinators. Important local authorities will also be roped in to address any emergency.	PI/Co-PI will be overall responsible for constituting the emergency preparedness team and liaison with local authorities.
<b>Other</b>					
41.	Does the grantee use any radioactive materials (isotopes tracers, radiation equipment, etc)?	Yes		Regular monthly surveillance	Periodic checks will be undertaken.
	Does the grantee have appropriate radioactive material and waste storage and disposal system in place?		No		
	Are radioactive warning signs in place?		No		
42.	Is the lab/room air regularly checked for microbial contamination?		No		Air quality (microbiological) will be checked on monthly

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					basis w. e. f. 1 May 2020
43.	Are there any odor control measures in place?	Yes		Adequate facilities for ventilation, Negative pressure chambers, and exhaust fans are available to control the odor.	The ventilation and air exhaust status will be routinely monitored.
44.	Are fume hoods and exhausts regularly checked and maintained?	Yes		The electrical staff maintains this.	
45.	Does the grantee use DG set > 15 KVA?		No		procurement of DG >15KVA will be processed.
	Does the grantee have consent for DG > 15 KVA?				
	Are emissions from boilers and DG sets regularly monitored to be within the prescribed norms?		No		
46.	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?	Yes		The disposal of solid and plastic wastes is done by the Municipal Corporation on daily basis.	Regular activity will be followed and reviewed.
47.	Is wastewater treated separately by the grantee? (Liquid waste from laboratory, chemicals, fluids, solvents, medium and cultures, coolants, etc.)	Yes		Types of wastewater: Culture media  Treatment of wastewater: Autoclave  Chemical management in wastewater treatment plants: No	
48.	Are there any settlements, water bodies, cultivated land, or any other eco-sensitive areas near the grantee's premises?		No	Not within 500m radius	
49.	Are there any buffers, fire vehicle routes in the grantee's premises?	Yes		Our center is well connected with concrete road and adequate space is available within the premises for fire.	NIE will ensure the same in future

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.