

Environmental Health Risk Management Plan (EHRMP)

Society for Health Allied Research and Education India (SHARE INDIA)

Proposal entitled Harnessing a population-based cohort for an epidemiological study on Dengue and Chikungunya and drive capacities to conduct clinical Trials.

1. Institutional Arrangements

<p>(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.</p> <p>(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.</p>					
Institutional Arrangement					
		Yes	No	Details	Proposed Plan
1.	Is there a designated full-time staff for Environment Health and Safety (EHS) issues?		NO	There is no full-time staff for EHS. However, issues shall be tackled on case to case basis	Based on the Project requirement a Consultant will be hired on need basis
2.	Does the EHS staff handle the following?				Based on the Project requirement a Consultant will be hired on need basis
	Occupational Health and Safety		NO		
	Waste Management		NO		
	List of consents and regulatory clearances		NO		
	Record keeping of accidents and procedures		NO		
	EHS trainings for staff		NO		
	Environment Management Framework compliance for Innovate in India Project		Yes	Will comply with the NBM BIRAC environment framework	
3.	Is there a reporting structure in place regarding EHS issues?		NO	Describe:	This structure will be put in place contingent to clinical trials and consultation with BIRAC in future.
4.	Are regular EHS trainings provided to staff?		NO	Frequency:	This will be done contingent to clinical

Environmental Health Risk Management Plan (EHRMP)

Society for Health Allied Research and Education India (SHARE INDIA)

					trials and consultation with BIRAC in future.
5.	Institutional Bio-Safety Committee (IBSC)		NO		Biosafety committee is not existing at SHARE INDIA currently. If required contingent to clinical trials and consultation with BIRAC in future will be put in place
6.	Ethics Committee (EC)	Yes		All research proposals from SHARE INDIA are submitted for review to MediCiti Ethics Committee operating under the aegis of SHARE INDIA's affiliate Mediciti institute of medical sciences (MIMS)	There are currently 6 external members of the total 15 members in the Ethics Committee. Ethics Committee meets on a monthly basis and as and when it is required for with an advanced notice.
General Occupational Health and Safety					
7.	Are there Standard Operating Procedures for accidents, hazards, and other emergencies (chemical spills, heat hazards, fire hazards, radioactive hazards etc.)?	YES		Most of these requirements are for a healthcare service delivery organization and SHARE INDIA is not a healthcare service delivery organization. Currently we have a SOP for fire hazards.	However, in consultation with BIRAC if these are required SHARE INDIA can consider it in future
8.	Are the following in place?				Except for the fire extinguishers and first aid kit, all the other things are not
	Chemical spill kits		NO		
	Eye wash		NO		
	Shower stations		NO		

Environmental Health Risk Management Plan (EHRMP)

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First Aid Kit	YES		required as SHARE INDIA is not a healthcare service delivery organization or lab.
Fire Extinguishers	YES		
Register of accidents and injuries		NO	

Environmental Health Risk Management Plan (EHRMP)

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9.	Are proper signage and storage system in place?		NO		These processes are more relevant to healthcare organizations like hospitals or laboratories. SHARE INDIA is a Not for profit organization
	Display of Material Safety Data Sheet (MSDS) where relevant		NO		
	Display of emergency numbers and procedures (Person to Contact, Doctor, Ambulance, Fire Emergency, Police) displayed in all critical Places		NO		
	Signage across the facility (labs, storage, hazardous areas, etc.)		NO		
	Are flammable materials appropriately stored to prevent fire hazards?		NO		
10.	Are smoke detectors, fire alarms, automatic safety/shut off systems, overflow preventors, etc. in place and regularly maintained?		NO	List:	These are more relevant to laboratory or a hospital and are not relevant to SHARE INDIA
11.	Are there control measures for VOC, air emissions, high operating temperatures, pathogens/vectors etc. in place?		NO	List:	SHARE INDIA does not produce any of these emissions or high temperatures
12.	Are regular mock drills conducted for emergency preparedness and safety?		NO	Frequency (type wise):	SHARE INDIA is not a place of healthcare delivery or laboratory and this is not relevant to it
13.	Are staff provided with OHS training?		NO	Describe:	
Biomedical Waste (BMW)					
14.	Is there generation of biomedical waste (as described in Bio-Medical Waste Management Rules, 2016) in the grantee?	Yes		Needles, syringes, lancets, vacutainers used for point of care testing and blood sample collection in the field at the household level of the participants will be safely transported.	The Transportation will be done in their respective containers to the Medciti Institute of Medical sciences (MIMS) which is an affiliate of SHARE INDIA for proper disposal. MIMS has SOPs in place for discarding biomedical waste including an MoU with an agency licensed for biomedical waste disposal.

15.	Is there trained staff to handle biomedical waste in the grantee?	YES				
16.	Has the grantee obtained authorization from State Pollution Control Board /Pollution Control Committee?	YES		MIMS has obtained the authorization		
17.	Is the biomedical waste segregated at point of generation in the facility and stored in suitable containers?	YES		Yellow	YES	Compliance with the regulations of the biomedical waste management rules for biomedical waste segregation, storage and disposal are monitored by Housekeeping in charge
				Red	YES	
				White	YES	
				Blue	YES	
18.	Is the bar code system for the segregated waste in place?	YES		The BMW agency provides the barcoded bags which are used for segregation		
19.	Is the biomedical waste being sent to an authorized common BMW facility?	YES		Name and address of CBMWF: Roma Industries 12-225, Adarshnagar, IDPL Colony, Qutbullapur, R.R. District – 500037 Distance from facility: About 15 kilometers Frequency and Mode of transport: Daily – Closed Van Who transports? Roma Industries		

20.	Does the grantee have an in-house BMW treatment facility?	NO		Reason: SHARE INDIA uses the MIMS facility for BMW generated and MIMS does not have in-house BMW treatment Authorization: Distance of nearest CBWM from facility: Types of treatment:	The facility where the BMW management is done is in the same campus where SHARE INDIA is located, it will be done at MIMS> The address of the facility is MIMS, Ghanpur Village, Medchal Mandal, Medchal District, Telangana 501401.
	Is the treatment facility own (individual)?	NO			
	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?	YES		Types of treatment: As per the SOPS of MediCiti Institute of Medical Sciences (MIMS)	Compliance calendar shall be maintained
22.	Is the liquid waste checked for active cells before sending to treatment plant?	YES		As per the SOPS of MediCiti Institute of Medical Sciences (MIMS)	Regular monitoring shall be undertaken
23.	Are necessary waste pre-treatment equipment in place?	Yes		List of equipment: Autoclaves,	The pretreatment will be done as per the SOPS of the MIMS which are mentioned and also as per the BMW management rules.
	Do the equipment adhere to prescribed norms by State Pollution Control Board (SPCB)?	Yes		Details of waste pre-treatment: Chemical disinfectants using Sodium Hypochlorite and formalin solution	
24.	Are chlorinated plastic gloves and bags phased out in the grantee?	Yes		This is taken care by Roma Industries – Roma Industries 12-225,	

				Adarshnagar, IDPL Colony, Qutbullapur, R.R. District – 500037 This agency provides the biomedical waste management services after segregation and collection from MIMS	
25.	Are grantee's personnel involved in handling BMW provided with regular training?	Yes		Frequency: Refreshers will be provided once in six months Trainer: by the MIMS lab in charge on the BMW processes to be followed.	The Field staff and lab technician of SHARE INDIA will be trained at the start of the project,
26.	Are medical examination provided to personnel involved in BMW waste handling and are they provided with relevant immunization like Hepatitis B and Tetanus?	Yes		Frequency of medical examination: Once is six months This is being done for the MIMS staff	
27.	Is a daily register for biomedical waste maintained including accident reporting record?	Yes		Daily register is being maintained of the waste generated (weight).	
28.	Are annual reports on BWM submitted to SPCB as per required form (see Bio-Medical Waste Rules 2016)?	Yes		As per the requirements of the SPCB.	This practice will be checked periodically.
Hazardous Waste (HW) – SHARE INDIA in consultation with NBM will consider these to be implemented in future					

29.	Is there generation of hazardous waste (as per Hazardous Waste Rules, 2016) in the grantee?	No		If Yes, provide a list of hazardous waste produced in the facility If No, provide a list of all waste produced in the facility.	SHARE INDIA does not and will not generate any hazardous waste
E-Waste and Batteries - SHARE INDIA in consultation with NBM will consider this to be implemented in future					
30.	Does the grantee generate e-waste, produce or manufacture electrical and electronic equipment?	No			SHARE INDIA does not manufacture electrical equipment or generate significant e-waste. However, for the very minimal amount of e-waste generated if required SHARE INDIA will implement certain process for it in consultation with BIRAC.
31.	Has the grantee obtained SPCB authorization on e-waste?	NO			SHARE INDIA does not fall under the ambit of SPCB requirement
32.	Does the grantee channelize the e-waste to authorized recycling or disposal facility?	No		Name and address of disposal facility/ recycler: Inhouse or outsourced Facility:	This is currently not relevant to SHARE INDIA, however if it is required in the future it can be implemented in consultation with BIRAC
33.	Is there accident reporting and records in place?	No			This is not relevant to SHARE INDIA

34.	Are PPEs available to staff?	No			Not relevant to SHARE INDIA as it does not provide healthcare services or does lab activities.
35.	Is the grantee involved in manufacture of batteries?	No			SHARE INDIA does not manufacture batteries
36.	Does the grantee generate battery waste?	No			SHARE INDIA does not generate battery waste
37.	Does the grantee deposit the battery waste to registered recycler /dealer /manufacturer /reconditioner /collection center?	No		Name and address of battery waste receiving entity:	The minimal battery waste generated on the vehicles and UPS are deposited back to the retailer from where the next battery is purchased

Community Health and Safety and risk mitigation

38.	Safety Transportation Management System (for transport Of hazardous material)	YES		Lancets, needles, syringes, vacutainers used for blood sample collection in the field are transported in puncture proof containers filled with disinfectants to MIMS lab for safe temporary storage of the waste till it is cleared next morning by the biomedical waste handling agency operating under an MoU with MIMS. Blood samples collected from	This process will be followed periodically with proper checks and balances with the BMW agency.
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				participants in the field are transported in temperature-controlled bio-safety compatible equipment and stored in the MIMS laboratory before analysis. Any residual blood sample is segregated and disposed off as biomedical waste as per the standard guidelines under which the licensed MIMS laboratory operates.	
39.	Emergency preparedness and participation of local authorities and potentially affected communities	Yes		SHARE has built rapport with the individuals in the community, local leadership and the local administration through its past and ongoing community-based projects over the past twenty years.	The local community health workers and community leaders will be informed to inform about any issues that can affect the community
Other					
40.	Is the lab/room air regularly checked for microbial contamination?	Yes		These are done at the MediCiti Institute of Medical Sciences where SHARE INDIA lab work is done	Periodic checks will be done
41.	Are there any odor control measures in place?	Yes		These are done at the MediCiti Institute of Medical Sciences where SHARE INDIA lab work is done	Periodic cleaning will be done

42.	Are fume hoods and exhausts regularly checked and maintained?	Yes		These are done at the MediCiti Institute of Medical Sciences where SHARE INDIA lab work is done	Periodic checks will be done and maintained
43.	Does the grantee use DG set > 15 KVA?	Yes			
	Does the grantee have consent for DG > 15 KVA?	Yes			
	Are emissions from boilers and DG sets regularly monitored to be within the prescribed norms?	Yes			
44.	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 solid waste (including plastic waste) in the facility and campus is segregated and disposed as per the current rules.	
45.	Is wastewater treated separately by the grantee? (Liquid waste from laboratory, chemicals, fluids, solvents, medium and cultures, coolants, etc.)	Yes		Types of wastewater: Treatment of wastewater: Sewerage Treatment Plant (STP) Capacity 50 KL Chemical management in wastewater treatment plants:	
46.	Are there sludge management and cut off drains in place for wastewater?	Yes		The campus has sludge management and drains present	Will be done as per the BMW 2016 rules
47.	Are there any settlements, water bodies, cultivated land, or any other eco-sensitive areas near the grantee's premises?	Yes		Describe: Distance from premises:	SHARE INDIA is located close to a village and cultivable lands;

					however, it does not and will not generate any hazardous or radioactive waste.
48.	Are there any buffers, fire vehicle routes in the grantee's premises?	Yes		Proper metal roads are available, but no separate routes	There will be enough provision of parking or space for vehicles

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.