

Environmental Health Risk Management Plan (EHRMP)

The INCLIN Trust International

Proposal entitled “Burden and Factors influencing the Epidemiology of Dengue & Chikungunya at Existing Demographic Developmental & Environmental Surveillance Site SOMAARTH-DDESS, Palwal and Site Preparation for Regulatory Compliant Field-based Vaccine Trials”

1. Institutional Arrangements

- (i) Brief description of the proposed activity: The main objectives of the proposed study are (1) to conduct community based longitudinal Incidence study of Dengue and Chikungunya diseases and (2) to establish GCP compliant field site for conduct of vaccine trials in future.
- (ii) List of environments related regulatory clearances required for the activity are mentioned in the sections given below.

Institutional Arrangement		Yes	No	Details	Proposed Plan
1.	Is there a designated full-time staff for Environment Health and Safety (EHS) issues?		No	The proposed project is an observational study focusing on the epidemiology of Dengue and Chikungunya diseases. It does not cover any interventions which may cause environment health and safety issues.	Based on the requirement a Consultant will be hired on need basis alternatively one full time position for EHS engineer is planned when community based clinical trial or interventions will be undertaken.
2.	Does the EHS staff handle the following?		No	Currently EHS staff is not available. Occupational Health Safety handling is conducted by the trained clinicians, and lab staff.	Obtaining No Objection Certificate (NOC) from State pollution Control Board (SPCB) for Microbiology Lab, e-waste, bio waste is in process.
	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		Even though EHS is not available, all the activities conducted at the field site are keeping in mind the Environment Management Framework	Once approval/registration is done, all staff dealing with above shall be trained in consultation with SPCB and other authorities.

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3.	Is there a reporting structure in place regarding EHS issues?	Yes		INCLEN's Standard Operating Procedure (SOP) on Biosafety is in place.	SOP will be updated incorporating the amendments taking place in the existing Biosafety laws.
4.	Are regular EHS trainings provided to staff?		No	Frequency: Training calendar will be prepared on the basis of the anticipated risks in the proposed activity.	Staff EHS trainings will be planned periodically following a training calendar. Board (SPCB).
5.	Institutional Bio-Safety Committee (IBSC)		No	No genetic research being conducted currently.	In future, as and when need will arise IBSC will be established
6.	Ethics Committee (EC)	Yes		INCLEN's Institutional Ethics Committee comprises of 11 external members including a chairperson and 1-member secretary (permanent employee of the INCLEN) is in place.	Quality Assurance Manager is in place to monitor project adherence with respect to the Standard Operating Procedures on regular basis.
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		Standard Operating Procedure (SOP) for biosafety are in place and followed by the project staffs.	This will be centrally monitored and controlled by Chief operational officer (COO) and respective project managers whereas at field sites the site manager (Station Manager) will ensure compliance and give report to COO on monthly bases on occurrence.
8.	Are the following in place?			Biosafety	Regularly reviewed
	Chemical spill kits		No	measures currently	and new safety

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	Eye wash		No	available at the	measures are added based on the identified risks.
	Shower stations		No	organization and	
	First Aid Kit	Yes		its field sites are	
	Fire Extinguishers	Yes		based on the	
	Register of accidents and injuries	Yes		identified occupational risks.	

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9.	Are proper signage and storage system in place?	Yes			
	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			
10.	Are smoke detectors, fire alarms, automatic safety/shut off systems, overflow preventors, etc. in place and regularly maintained?	Yes		Water/Fire hydrant and fire extinguishers are installed. Mock drill is conducted. Miniature circuit breaker (MCB) for electrical hazards for prevention of short circuit and electric fire hazards.	Fire alarms and smoke detectors shall be installed within 6 months.
11.	Are there control measures for VOC, air emissions, high operating temperatures, pathogens/vectors etc. in place?		No	No air, noise or pathogen related pollution generated at the field site.	
12.	Are regular mock drills conducted for emergency preparedness and safety?	Yes		Frequency (type wise): Every 6 month	As per the standard operating procedures (SOPs) all the staff shall be trained and record of the same maintained in the register including mock drills.
13.	Are staff provided with OHS training?	Yes		Lab and clinic staff are trained in Occupational Health Safety (OHS) practices.	Regular OHS trainings as a part of biosafety are planned.
Biomedical Waste (BMW)					

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14.	Is there generation of biomedical waste (as described in Bio-Medical Waste Management Rules, 2016) in the grantee?	Yes		Bio waste generated from the facility include general medical waste (used gauge, syringe, cotton, papers) which are generated from the day care clinics and basic microbiology lab setup at the field site. Bio Medical Waste (BMW) generated from the facility are safely collected and disposed by the external agency (district BMW facility through Community Health Centre).	State Pollution Control Board has been contacted and registration process for bio-waste and e-waste is in progress.								
15.	Is there trained staff to handle biomedical waste in the grantee?	Yes		Clinic staff (Doctors and Nurses) and Laboratory personnel are trained in Bio Waste Management.	This will be an ongoing process.								
16.	Has the grantee obtained authorization from State Pollution Control Board /Pollution Control Committee?		No	Authorization and registration is under due process.	Authorization and registration from State Pollution Control Board/ Pollution Control Committee is under progress.								
17.	Is the biomedical waste segregated at point of generation in the facility and stored in suitable containers?	Yes		<table border="1"> <tr> <td>Yellow</td> <td>Yes</td> </tr> <tr> <td>Red</td> <td>Yes</td> </tr> <tr> <td>White</td> <td>Yes</td> </tr> <tr> <td>Blue</td> <td>Yes</td> </tr> </table>	Yellow	Yes	Red	Yes	White	Yes	Blue	Yes	Will be treated as per Bio-Medical Waste Management (Amendment) Rules, 2018
Yellow	Yes												
Red	Yes												
White	Yes												
Blue	Yes												
18.	Is the bar code system for the segregated waste in place?		No		Bar coding system shall be implemented once the clearance from SPCB is obtained and a MoU with								

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					collecting agency is entered into External agency for this has already been identified.
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19.	Is the biomedical waste being sent to an authorized common BMW facility?	Yes		<p>Name and address of CBMWF: Community Health Centre (CHC) Aurangabad, Palwal</p> <p>Distance from facility: <1 Km</p> <p>Frequency and Mode of transport: every alternate day</p> <p>Who transports? BMW staff of CHC which has entered into an agreement with an outside authorized agency for collection of bio-waste.</p>	
20.	Does the grantee have an in-house BMW treatment facility?	No		<p>Reason: Common Bio Waste Management Facility (CBMWTF) available within 1 Km at nearest health facility i.e. CHC</p> <p>Authorization: State Government</p> <p>Distance of nearest CBMWTF from facility: < 1Km</p> <p>Types of treatment: From CHC, Aurangabad, BioWaste is transported to District Hospital Palwal, where bio waste is treated and managed using</p>	As the organization outsources the entire BMW to external authorized agency, there is no plan to establish in-house facility currently.
	Is the treatment facility own (individual)?	No			
	Is the treatment facility a shared facility in an industrial park?	No			

				incinerator, autoclave and other facilities.	
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: Bio waste pretreated. All sharp wastes pre-treated in 1% sodium hypochlorite solution.	Compliance calendar shall be maintained
22.	Is the liquid waste checked for active cells before sending to treatment plant?		No		This will be planned as and when the project starts.
23.	Are necessary waste pre-treatment equipment in place?	Yes		List of equipment: Autoclaves and shredders are used in house.	
	Do the equipment adhere to prescribed norms by State Pollution Control Board (SPCB)?	Yes		Details of waste pre-treatment: All sharp wastes pre-treated in 1% sodium hypochlorite solution.	
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?		No	Frequency: NA Trainer: NA	Regular trainings for the BMW management will be planned.
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: Quarterly	This practice will be followed periodically.
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		State Pollution Control Board approval is in progress and once it is obtained, annual reports will be submitted as per the biomedical waste management rules.
Hazardous Waste (HW)					
29.	Is there generation of hazardous waste (as per Hazardous Waste Rules, 2016) in the grantee?		No	No hazardous waste is generated at the facility by the grantee.	
30.	Is there trained staff in the facility to identify and handle hazardous waste?		No	Hazardous wastes are identified by the qualified personal with the help of the hazardous waste list provided by the Government of India (Hazardous waste material rule 2016).	Based on the requirement an Environmental Health Staff will be hired on need basis.
E-Waste and Batteries					
31.	Does the grantee generate e-waste, produce or manufacture electrical and electronic equipment?	Yes		E-waste of nominal quantities are generated by the grantee and disposed as per the INCLEN's e waste management policies.	Registration process will be initiated to attain approvals in this field by State Pollution Control Board.
32.	Has the grantee obtained SPCB authorization on e-Waste?		No		Authorization will be obtained from the State Pollution Control Board (SPCB).
33.	Does the grantee channelize the e-waste to authorized recycling or disposal facility?	Yes		Name and address of disposal facility/ recycler: Endeavor Reprocessor & Recycler's India, plot no 323, Sector 24, Industrial	As per SOPs, INCLEN will review the holding of e-waste including batteries on yearly basis. The authorized agency will be contacted for the

				Area, Faridabad, Haryana has been identified through SPCB, Palwal and registration process is in progress.	collection of e-waste generated.
34.	Does the manufacturing grantee have Extended Producer Responsibility system and EPR-authorization in place?		No	Describe: Grantee does not involve in any kind of manufacturing / production.	
35.	Does the grantee maintain a record of collection, storage, sale and transport of e-waste?	Yes		Registration with an authorized agency is in progress.	The review of e-waste generated will be done on yearly basics and the authorized and identified agency will be contacted for collection of any e-waste requiring disposal.
36.	Does the grantee submit annual reports on e-waste to SPCB?		No		Permission from State Pollution Control Board (SPCB) will be taken.
37.	Is there accident reporting and records in place?	Yes		Accident reporting and recording mechanism is in place.	Chief Operations Officer will be the authority for reporting any such accidental cases. In addition, each field site will report accidents to station managers first.
38.	Are PPEs available to staff?	Yes		Personal protection equipment (PPE) for doctors, lab staff and staff handling the waste are available and in use.	The requirement and availability of stocks for PPEs will be regularly reviewed and maintained. Will ensure providing PPEs to staff at all times on a regular basis.
39.	Is the grantee involved in manufacture of batteries?		No		
40.	Does the grantee generate battery waste?	Yes		Batteries in UPS, mobile devices and electric invertors are in use.	These will be disposed off as per guidelines of SPCB.

41.	Does the grantee deposit the battery waste to registered recycler/dealer/manufacturer/re-conditioner/collection center?	Yes		Name and address of battery waste receiving entity: Concerned battery manufacturer / vendor Endeavor Reprocessor & Recycler's India, Plot no 323, Sector 24, Industrial Area, Faridabad, Haryana, India	
42.	In case of manufacturing, does the grantee comply to Battery Management Rules 2000 and ensure collection of old batteries?	Yes		Grantee does not manufacture battery but battery management is in place for the batteries used in the electronic and mobile devices.	
Community Health and Safety and risk mitigation					
43.	Safety Transportation Management System (for transport of hazardous material)	Yes		No hazardous waste is generated at the facility. Bio medical waste generated at the facility are safely transported to the treatment facility.	
44.	Emergency preparedness and participation of local authorities and potentially affected communities	Yes		Local authorities and communities will be involved in the project from the beginning till the end. Emergency preparedness is part of the Administrative standard operation plan of INCLIN.	
Other					
45.	Does the grantee use any radioactive materials (isotopes tracers, radiation equipment, etc)?		No		
	Does the grantee have appropriate radioactive material and waste storage and disposal system in place?		No	Describe: Organization does not use any radioactive material (nuclear	This capacity can be built in future for conducting nuclear medicine related

				medicine) and there is no storage and disposal system in place for such materials.	studies.
	Are radioactive warning signs in place?		No	Organization does not use any radioactive material (nuclear medicine) and there is no storage and disposal system in place for such materials.	This capacity can be built in future for conducting nuclear medicine related studies.
46.	Is the lab/room air regularly checked for microbial contamination?		No	It is a part of the lab protocol when any activity is performed at the field site laboratory microbial monitoring is followed but currently field site lab is non-functional.	All the related activities will be monitored and checked on the site lab being functional.
47.	Are there any odor control measures in place?	Yes		Exhaust fan (1440 rpm) is in place at the lab.	This will be regularly checked and maintained.
48.	Are fume hoods and exhausts regularly checked and maintained?	Yes		Regular cleaning and maintenance of ventilating system takes place.	
49.	Does the grantee use DG set > 15 KVA?		No	DG set > 15 KVA is not in place at the field site office.	
	Does the grantee have consent for DG > 15 KVA?		No		
	Are emissions from boilers and DG sets regularly monitored to be within the prescribed norms?		No		
50.	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		Describe: Organic (kitchen, lawn wastes) and inorganic (plastic, papers, bottles) domestic solid waste are stored separately in designated bins. Organic waste is	Regular activity followed and reviewed.

				converted into the compost at the field site and other solid wastes are collected and disposed-off by the municipal waste collectors.	
51.	Is wastewater treated separately by the grantee? (Liquid waste from laboratory, chemicals, fluids, solvents, medium and cultures, coolants, etc.)		No	Types of wastewater: Treatment of wastewater: Currently this has not been in place. Chemical management in wastewater treatment plants: NA Field site is located at the rural area where waste water collection and disposal are not currently available.	A system for liquid waste water management will be planned and set up in consultation with state pollution control board.
	Are there sludge management and cut off drains in place for wastewater?		No	In rural areas waste water sewerage system is not in place.	Grantee will contact local municipal/panchayat office for building the infrastructure for waste water disposal.
52.	Are necessary provisions for noise cancellation in place?		No	Describe: Grantee does not generate excessive noise which required to be cancelled.	
53.	Are there any settlements, water bodies, cultivated land, or any other eco-sensitive areas near the grantee's premises?	Yes		Describe: Ponds and agricultural fields at about 500 meters but currently not affected as no hazardous waste is generated, used for disposed off in the premises. Distance from premises: 500	

				meters	
54.	Are there any buffers, fire vehicle routes in the grantee's premises?	Yes		The site is located in a village of Palwal District of Haryana. Site office is in a single-story building with good access from main road. Fire tenders can easily enter through its front gate. The fire tender can reach to any place/office and room of the site office as it has big entrance gate. From the sides of the building, there is an open space to deal with any emergency.	The site will install four fire extinguishers to deal with any fire emergency. Office building will have good accessibility and in case of emergency underground water tank of about 8000 litre capacity will be available and will be maintained regularly. Further there will be a functional bore well within the premises.

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.

