The INCLEN Trust International

Proposal entitled: <u>SOMAARTH e-Data Management Platform for quality assured electronic data</u> <u>collection, documentation, reporting, analysis and archival of community based demographic,</u> <u>developmental & environmental surveillance sites and associated research studies</u>

1. Institutional Arrangements

(i) Brief description of the proposed activity

INCLEN proposes to develop an enhanced version of e-platform with an overarching goal to comprehensively manage full life-cycle of projects from initiation to archival. Existing e-platform includes a static software for demographic surveillance SOMAARTH-1 and a dynamic & customizable software for study designs SOMAARTH-3. Proposed activities are to incorporate enterprise-based GIS solutions in the e-platform, to develop web-based metadata module as per DDI International standards, to enhance descriptive analytical capabilities through dynamic report builder modules and IT support to sites during study.

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(ii)	List of environments r	elated regulatory cl	earances required for	the activity
(11)		enaled regulatory er	curunees required for	the detry leg.

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1.	No objection of	certificate form	State poll	ution control bo	ard shall be ob	tained for e-waste

	Institutional					
	Arrangement	Yes	No	Details	Proposed Plan	
1.	Is there a designated full-time staff for Environment Health and Safety (EHS) issues?		No	data management. It does not cover any interventions which may cause environmental health and safety issues.	Based on the requirement a Consultant may be hired on need basis alternatively one full time position could be created during the second phase when community based clinical trial or interventions will be launched.	
2.	Does the EHS staff handle the following?		No	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. Once approval/registration is done, all staff dealing with above shall be trained in consultation with SPCB and other authorities.	
	Occupational Health and Safety		No		The services of	
	Waste Management		No]	Environmental Expert will	

	List of consents and regulatory clearances Record keeping of accidents and procedures EHS trainings for staff Environment Management Framework	Yes	No No No	Even though EHS is not	also be availed as and when required.
	in India Project			available, all the activities conducted at the field site are keeping in mind the Environment Management Framework	
3.	Is there a reporting structure in place regarding EHS issues?	Yes		INCLEN's Standard Operating Procedure (SOP) on Biosafety is in place.	
4.	Are regular EHS trainings provided to staff?		No	Frequency:	Staff EHS trainings are planned. Frequency shall be as per guidelines of State pollution Control 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 Occ	upatio	onal H	lealth 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?				Regularly reviewed and new
	Chemical spill kits		No	currently available at the	safety measures are added
	Eye wash		No	organization and its field	based on the identified risks.
	Shower stations		No	sites are based on the	
	First Aid Kit	Yes		identified occupational	
	Fire Extinguishers	Yes		risks.	
	Register of accidents and injuries	Yes			
9.	Are proper signage and storage system in place?	Yes		Chief operational officer and respective project	Regular feedback has been executed and six-monthly
	Display of Material Safety Data Sheet (MSDS) where relevant	Yes		managers whereas at field sites the site manager	reports with photographs shall be sought from each
	Display of emergency numbers	Yes			site and a central register for
	and procedures (Person to			regularly.	the same will be maintained.
	Contact, Doctor, Ambulance,			i og unun i j i	
	Fire Emergency, Police)				
	displayed in all critical				
	places	37		_	
	Signage across the facility	Yes			
	(labs, storage, hazardous areas, etc.)				
	Are flammable materials	Yes		-	
	appropriately stored to prevent	105			
	fire hazards?				
10.	Are smoke detectors, fire	Yes		Water/Fire hydrant and	Fire alarms and smoke
	alarms, automatic			fire extinguishers are	detectors shall be installed
	safety/shutoff systems,			installed.	within 6 months.
	overflow preventors, etc. in			Mock drill are conducted.	
	place and regularly			Miniature circuit breaker (MCB) for electrical	
	maintained?			hazards for prevention of	
				short circuit and electric	
				fire hazards.	
11.	Are there control measures for		No	No air, noise or pathogen	No air, noise or pathogen
	VOC, air emissions, high			related pollution generated	
	operating temperatures,			at the field site.	at the Head office or the
	pathogens/vectors etc. in place?				field site.
12.	Are regular mock drills	Yes		Frequency (type wise):	A a non the standard
12.	conducted for emergency	1 es		Every 6 month	As per the standard
	preparedness and safety?				operating procedures (SOPs) all the staff shall be trained
	preparedness and burety.				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?	No	Lab and clinic staff at field site are trained in Occupational Health Safety (OHS) practices.	Regular OHS trainings as a part of biosafety are planned.
		Biomedica	l Waste (BMW)	
14.	Is there generation of biomedical waste (as described in Bio-Medical Waste Management Rules, 2016) in the grantee?	No	This project does not involve any use of biomedical items and hence no biomedical waste is and will be generated.	This project is for software development and data management which will be done at INCLEN head office, where no biomedical waste is generated, hence this section is not applicable.
	Haza	ardous Wa	nste (HW)	
15.	Is there generation of hazardous waste (as per Hazardous Waste Rules, 2016) in the grantee?	No	 No hazardous waste is generated at head office where this project shall be conducted. For the sites, list of all waste produced in the facility. (Currently only domestic waste -solid and liquid) and general clinical waste are generated. Solid waste: 1- Organic: kitchen, agriculture/ lawn, 2- Inorganic: Paper, bottle, plastic, mettle 3- Biomedical: Gauge, dressings, syringes, unused medicines. Liquid waste from kitchen and washrooms. 	No hazardous waste is generated as this project is on software development.
16.	Is there trained staff in the facility to identify and handle hazardous waste?	No	No hazardous waste is generated at head office where this project shall be conducted. For the sites, at	
			sites, hazardous wastes are identified by the qualified personal with the help of the hazardous waste list	

23.	annual reports on e-waste to		INO	done by SPCB, reports	Pollution Control Board
22. 23.	Does the grantee maintain a record of collection, storage, sale and transport of e-waste? Does the grantee submit	Yes	No	ë .	The review of e-waste generated is done on yearly basics and in case there are any e-waste requiring disposal the authorized and identified agency is contact for collection. Permission from State
21.	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.	The INCLEN does not involved any kind of manufacturing/production.
20.	Does the grantee channelize the e- waste to authorized recycling or disposal facility?	Yes		Industrial Area, Faridabad, Haryana has been identified through SPCB, Palwal and registration process is in progress.	As per SOPs, INCLEN reviews the holding of e- waste including batteries on yearly basis. If some e-waste is available for disposal, the authorized agency is contacted for the collection of e-waste
19.	Has the grantee obtained SPCB authorization on e-waste?		No	State pollution control board has been approached for registration. Authorized agency for collection of e-	Authorization from State Pollution Control Board (SPCB) is in process.
18.	Does the grantee generate e-waste, produce or manufacture electrical and electronic equipment?	E-W Yes	aste a		Registration process is in progress with State Pollution Control Board.
				(Hazardous waste material rule 2016).	
				provided by the Government of India	

	records in place?			recording mechanism is in	the key person to whom all
				place.	such reporting is made. In addition, each field site reports accidents to station managers first.
25.	Are PPEs available to staff?	Yes		of Personal protection equipment (PPE) for the staffs at INCLEN head	The PPE involved for the project are head cap, coat, mask and gloves which shall be stocked for six months requirement. Therefore, shortages are unlikely.
26.	Is the grantee involved in manufacture of batteries?		No	-	We are not manufacturing batteries
27.	Does the grantee generate battery waste?	Yes		Batteries in UPS, mobile devises and electric equipment are in use.	These will be disposed off as per guidelines and directions of SPCB where registration process is on.
28.	Does the grantee deposit the battery waste to registered recycler/dealer/manufacturer/recon ditioner/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	As per SOPs, INCLEN reviews the holding of batteries including e-waste. If some batteries are available for disposal, the authorized agency is contacted for the collection of the batteries.
	Community	Healt	h and S	afety and risk mitigation	
29.	Safety Transportation Management System (for transport Of hazardous material)			manufacture or distribute hazardous material.	INCLEN is not dealing with hazardous material in anyway. And proposed proposal also does not required use of the transportation of hazardous material

30.	Emergency preparedness and participation of local authorities and potentially affected communities	Yes		involved in the project from the beginning till the end As per the protocol of the projects to be conducted at sites. Emergency preparedness is part of the Administrative standard operation plan of INCLEN.	medical officers) of the field
			0	ther	
31.	Does the grantee use any radioactive materials (isotopes tracers, radiation equipment, etc)?		No	used.	material is in use or shall be used, the regulatory provisions do not apply.
	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 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 if required. At present Since no radioactive material is in use or shall be used, the regulatory provisions do not apply.
32.	Are there any odor control measures in place?	Yes		Exhaust fan (1440 rmp) is in place at the lab.	The maintenance staff will keep a check on all electricity fitting for their functionalities.
33.	Does the grantee use DG set > 15 KVA?		No		Since the DG set in use is
	Does the grantee have consent for $DG > 15 \text{ KVA}$?		No	1	less than 15 KVA capacity, hence the various regularity
	Are emissions from boilers and DG sets regularly monitored to be within the prescribed norms?		No		provisions are not applicable.
34.	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		(kitchen, lawn wastes) and inorganic (plastic, papers, bottles) domestic solid waste are stored separately in designated bins. Organic waste is	For the waste disposal a team of one supervisor and two workers are employed. The supervisor monitors the proper in-house waste collection and liaise with municipal authorities for

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				compost at the field site and other solid wastes are collected and disposed-off by the municipal waste collectors.	waste disposal.
35.	Is wastewater treated separately by the grantee? (Liquid waste from laboratory, chemicals, fluids, solvents, medium and cultures, coolants, etc.)		No	Treatment of wastewater: Currently this is not in place as no Chemical management in wastewater is used, hence NA	A system for liquid waste water management needs to be planned in consultation with state pollution control board. Field site is located at the rural area where waste water collection and disposal are not currently available.
	Are there sludge management and cut off drains in place for wastewater?		No	undertaken in the notified industrial area which has	Grantee will contact local municipal/ panchayat office for building the infrastructure for waste water disposal.
36.	Are necessary provisions for noise cancellation in place?		No	•	There is no such equipment in use which are noisy.
37.	Are there any settlements, water bodies, cultivated land, or any other eco-sensitive areas near the grantee's premises?	Yes		in New Delhi	There are no water bodies, cultivated land or any other eco sensitive areas near INCLEN office.
38.	Are there any buffers, fire vehicle routes in the grantee's premises?	Yes		access to fire vehicle from front side of the building	It is two story building which is quite amenable for use of fire tenders in case of fire. In addition, fire hydrant is installed in the front of the building.

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.