

**Production of safe and effective oral cholera vaccine of global GMP standards in India
Through Industry Academia partnership to meet India's supply needs**

Translational Health Science & Technology Institute (THSTI)

Environmental and Health Risk Management Plan

1. Environmental Impact and risk mitigation

Risks	Project Specific Risk	Potential Impact	Mitigation Steps
Air Pollution	We are anticipating very minimal risk. However, during Lab assays, aerosols and liquid fume chemicals (organic/inorganic) Acids may cause Air pollution	This may contaminate the reagents and Acid mist sometime is irritating to eyes, nose and throat	Users will use Respirator approved for acid mists; rubber gloves; splash proof goggles; eyewash fountain and safety shower; rubber footwear; while working with such chemicals. All the chemicals will be opened in hood equipped with HEPA FILTER Bacterial work will be done under biosafety hood.
Water Pollution and Waste water treatment	Residual Buffers and media after assay performance may contain bacterial residues and uses of different salts may cause water pollution.	Water contamination	Before disposal of the contaminated reagents, it will be decontaminated as per GLP guidelines
Chemical waste	Chemical wastes can be hazardous and can contaminate the environment if not handled properly.	In this project, we are not using any highly toxic chemicals, thus expecting very minimal risk.	We will strictly follow Institutional biosafety guidelines LAB WORKER WILL BE TRAINED and will be informed about the hazards and how to handle the chemical waste.
Biological Waste	Bacterial culture and Clinical samples specific to the trial participants may have minimal risk on	We anticipate very minimal risk as we will process the samples and	IBSC approval and GLP practices will be strictly followed.

	health and environment.	bacterial culture under biosafety hood.	
Heavy metals	None of the chemical reagents contain heavy metal	We do not any anticipate risk.	We will take IBSC approval and GLP practices will be strictly followed.
Radiation Waste	We are NOT USING Radioactive materials. However, THSTI has separate facility for working with radioactive materials.	Thus, We do not anticipate risk.	We will take IBSC approval and GLP practices will be strictly followed.
Destruction/alteration of surrounding ecosystem	THSTI has identified separate Lab space within the existing buildings, thus it does not require to build new building by destructing the environment or ecosystems.	We do not anticipate any risk.	THSTI has environment safety committee and green plantation program is executed in a regular basis. THSTI also has solar panel to save the electricity.

2. Occupational Health and Safety and risk mitigation

Risks	Project Specific Risk	Potential Impact	Mitigation Steps
Heat Hazards	Heat may be generated due touse of some instrument like autoclave, hot air oven.	We are anticipating minimal risk.	BSL-2 lab practices and GLP practices for occupational safety will be strictly followed. Training of Manpower will be done before utilizing the instruments.
Chemical hazards, including fire and explosions	Chemical burn may cause due to use of organic and inorganic acid and salts and solvents.	We are anticipating minimal risk.	BSL-2 lab practices and GLP practices for occupational safety will be strictly followed. Training of Manpower will be done before utilizing the instruments.
Pathogenic and biological hazards	THSTI Lab will be using bivalent inactivated oral vaccine and the vaccinated sera for study. Blood borne risk of transmitting	We are anticipating minimal risk.	BSL-2 lab practices including use of gloves, lab coat, and GLP practices for occupational safety will be followed strictly. If any one

	infection may possible.		comes into contact with the serum samples, immediate precaution will be taken including washing hands with soap and wiping the areas with disinfectant.
Radiological hazards	We are not using any radioactive material.	We are not anticipating any risk.	BSL-2 lab practices and GLP practices for occupational safety will be followed strictly.
Noise	None may generate due to use of lab instruments,	We are anticipating very minimal risk.	BSL-2 lab practices and GLP practices for occupational safety will be strictly followed. Training of Manpower will be done before utilizing the instruments.
Process safety	None specific	None specific	BSL-2 lab practices and GLP practices for occupational safety. Training of Manpower

Community Health and Safety and risk mitigation

Risks	Project Specific Risk	Potential Impact	Mitigation Steps
Safety Transportation Management System (for transport of hazardous material)	Vaccinated Serum samples may need to transport from field to THSTI for the assessment. The samples will be transported maintaining the cold chain.	We are anticipating minimal risk to our end.	SOPs will be made and training for clinical sample transportation will be done before transporting the samples. Sufficient cool pack/dry ice will be kept if require.
Emergency preparedness and participation of local authorities and potentially affected communities	The project proposed at THSTI is basically a lab based work. Fire related risk may be there due to short-circuit or overload.	We are anticipating minimal risk to our end.	Institutional policies and procedures for emergency preparedness are in place. Fire safety and emergency evacuation training

		is done in a regular interval.
<p>In case your organization already has EHS guideline, please summarise the same. If not, please describe the impact because of hazardous material, release of chemicals, biologicals, management of catastrophic events like fire/explosion.</p> <p>THSTI has organized waste collection and disposal procedures. IBSC committee is operational for project approvals and inspection. Fire exit signs are placed and regular fire drills and trainings are conducted. THSTI has set procedures for the operation of the bioassay lab and the SOPs will be followed for maintenance of equipments, management of chemical and biological wastes. Manpower training is part of the management process.</p>		

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