



# RAJYA VOKKALIGARA SANGHA

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## PROJECT RISK MANAGEMENT PLAN

To comply with DBT, NBM, World Bank & BIRAC's mission to promote innovation and self-sufficiency in the biotechnology sector while striving to reduce any social and environmental risks in its activities **Rajya Vokkaligara Sangha**, Fund Recipients for the proposal entitled "**Establishment of Pneumococcal vaccine immunogenicity evaluation centre at CRL- Kempegowda Institute of Medical Sciences, Bangalore**" has identified the following risks related to Project, Environment (including occupational health and community) and during conduct of clinical trials (if applicable). Risk mitigation measures are being taken by **Central Research Laboratory** as defined in the following annexures:

- i) **Environmental and Health Risk Management Plan:** Compliance to corresponding legislations, Good practices in research and development methods, including while use of animals will be followed. We have referred to the Environment, Occupational Health and Safety Management Framework (EMF) document while preparing this annexure. Facility-specific occupational health and safety hazards have been identified based on risk assessment using established methodologies. The Community health and safety impacts related to handling and storage of solid, liquid and gaseous substances have been evaluated and accordingly mitigation measures will be implemented during project implementation. Impacts due to significant exposures to workers and potentially to surrounding communities, depending on quantities and types of accidentally released chemicals and biologicals have been thoroughly evaluated and addressed.

Project implementation site:

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## Environmental and Health Risk Management Plan

### 1. Environmental Impact and risk mitigation

Risks	Project Specific Risk	Potential Impact	Mitigation Steps
Air Pollution	Minimal Risk	Inadvertent contamination of air by bacteria	All bacterial work will be done in biosafety cabinet of BSL-2. Outgoing air from the area will pass through HEPA filters and burnout units.
Water Pollution and Waste water treatment	Minimal Risk	Inadvertent contamination of water	All liquid waste will be treated in effluent treatment plant (ETP) before discharge
Chemical waste	Minimal Risk	Some chemicals used in the laboratory which are carcinogenic may impact	Manufacturers instruction will be followed for the disposal of the chemical waste
Biological Waste	Minimal Risk	Inadvertent contamination with bacteria	Biological waste management system in place.
Heavy metals	Minimal Risk	Project implementation aspects will not create any adverse heavy metals waste.	Not required
Radiation Waste	Minimal Risk	Project implementation aspects will not create any adverse radiation metals waste	Not required
Destruction/alteration of surrounding ecosystem	Minimal Risk	Project implementation does not involve any destruction/alteration of surrounding ecosystem	Not required

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## 2. Occupational Health and Safety and risk mitigation

Risks	Project Specific Risk	Potential Impact	Mitigation Steps
Heat Hazards	Minimal Risk	Steam from the autoclave may cause burn related issues.	Procedure for handling the autoclave is in place. PPE is worn when handling. First aid kits and emergency measures are in place.
Chemical hazards, including fire and explosions	Minimal Risk	Injury to the staff and property loss	Chemicals used for the laboratory are stored in ventilated cupboards. Fire accident training is given to the working staff in the laboratory.
Pathogenic and biological hazards	Minimal Risk	Exposure to pathogens may occur during isolation and growth of micro-organisms in Laboratory	Use of personal protective equipment while performing the laboratory work. All the specimens are handled in biosafety cabinet.
Radiological hazards	Minimal Risk	Project implementation does not involve any use of radiological materials nor its creation	Not applicable
Noise	Minimal Risk	Project implementation aspects does not create any noise	Not applicable.
Process safety	Minimal Risk	Engineering and equipment maintenance shall be undertaken as per SOP's	Trained personnel is in charge of the engineering and equipment maintenance. Engineering controls are in place.

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### 3. Community Health and Safety and risk mitigation

Risks	Project Specific Risk	Potential Impact	Mitigation Steps
Safety Transportation Management System (for transport of hazardous material)	Minimal Risk	Minimal	Safety transportation as per SPCB guidelines by SPCB approved contract organization.
Emergency preparedness and participation of local authorities and potentially affected communities	Minimal risk	Minimal	Onsite emergency plan, mock drills, communication is in place. Details of the project and information is shared with Bangalore Municipal corporation

In case your organization already has **EHS guideline**, please summarise the same.

Environment, occupational health and safety management framework is being used as reference for implementation of identification, assessment, monitoring, evaluation and compliance to the Occupational Health, Safety and Environmental aspects associated with scientific projects.

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.

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