**Environmental Health Risk Management Plan (EHRMP)**

**Biological E. Limited**

**Proposal entitled:** "To develop a safe, immunogenic & stable vaccine for all populations against the novel coronavirus COVID-19 which is affordable and accessible for all countries"

(i) Brief description of the proposed activity :

To develop a vaccine against COVID-19 based on the antigen derived from the Receptor Binding Domain RBD of the Spike Protein S on the surface of SARS-CoV-2, and to demonstrate vaccine safety and efficacy immunogenicity in Phase I clinical study. The entire project is phased into Development, Scale-up & GMP manufacturing till pilot scale, Pre-clinical Toxicology studies, and Phase I Clinical studies.

(ii) List of environment related regulatory clearances required for the activity.
Authorizations from SPCB is available

**Institutional Arrangement**

| **Area of Risk** | | **Yes** | **No** | **Details** | **Proposed Plan** |
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| 1. | Is there a designated full-time staff for Environment Health and Safety (EHS) issues? | Yes | | There is a dedicated full time EHS staff. | The concerned staff will be trained on the Environment Health and Safety (EHS) and will comply with the norms |
| 2. | Does the EHS staff handle the following? | | | The dedicated EHS staff handles all the Occupational Health and Safety measures, ensures effective Waste management, maintain list of consents and regulatory clearances, records and monitors the accidents and all EHS related procedures. The staff conducts periodic trainings on EHS | We will comply to Environment Management Framework compliance for Innovate in India Project |
| | Occupational Health and Safety | Yes | | | |
| | Waste Management | Yes | | | |
| | List of consents and regulatory clearances | Yes | | | |
| | Record keeping of accidents and procedures | Yes | | | |
| | EHS trainings for staff | Yes | | | |
| | Environment Management Framework compliance for Innovate | Yes | | | |

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| | in India Project | | | | |
| 3. | Is there a reporting structure in place regarding EHS issues? | Yes | | We have a dedicated EHS team who reports to EHS head, who in turn reports to COO. | SOPs and formats to record any incidents and EHS issues will be structured as a part of EHS policy. |
| 4. | Are regular EHS trainings provided to staff? | Yes | | Frequency: Monthly | |
| 5. | Institutional Bio-Safety Committee (IBSC) | Yes | | | IBSC meetings are in place regularly for the approvals of the projects. The work will start once the IBSC approval is obtained |
| 6. | Ethics Committee (EC) | Yes | | | IEC meetings will be conducted on project-to-project basis and committee will review the safety and ethical aspects of the project. |
| **General Occupational Health and Safety** | | | | | |
| | **Area of Risk** | **Yes** | **No** | **Details** | **Proposed Plan** |
| 7. | Are there Standard Operating Procedures for accidents, hazards, and other emergencies (chemical spills, heat hazards, fire hazards, radioactive hazards etc.)? | Yes | | We have established SOPs as per the ISO standards.<br>BEIMSP 26.03 – Reporting and investigation of incidents/ accidents<br>BE IMSP 11.05 – Hazard identification and risk assessment<br>BE IMSP 24.03 – Spill control management | SOPs and formats to record any accidents, hazards, and other emergencies are there. |

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| | | | | BE IMSP 16.06 – Emergency response and preparedness.<br><br>And many other SOPs. | |
| 8. | Are the following in place? | | | All are located at strategic locations for easy accessibility | Registers are maintained for ensuring provisions of such requisites. |
| | Chemical spill kits | Yes | | | |
| | Eye wash | Yes | | | |
| | Shower stations | Yes | | | |
| | First Aid Kit | Yes | | | |
| | Fire Extinguishers | Yes | | | |
| | Register of accidents and injuries | Yes | | | |

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| 9. | Are proper signage and storage system in place? | | | All details are printed on a sheet with visible fonts size and placed located at strategic locations for easy accessibility and readability | Facilities will be upgraded with the activities increased. |
| | 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 | | List: We have approximately 15 Nos Fire Alarm Panels and almost 2180 detectors across the facility. | Facilities will be maintained and upgraded with the activities increased. |
| 11. | Are there control measures for VOC, air emissions, high operating temperatures, pathogens/vectors etc. in place? | Yes | | List: Scrubbers are used to control VOC emissions; UV light is used to control the pathogens. | Preventive measures with all precautions will be put in place as and when required during the project. |
| 12. | Are regular mock drills conducted for emergency preparedness and safety? | Yes | | Frequency (type wise): Once in Six months | |
| 13. | Are staff provided with OHS training? | Yes | | Describe: Monthly trainings are conducted on different topics related to OHS. | All the staff will be provided with trainings including newly joined staff. |
| | **Biomedical Waste (BMW)** | | | | |
| | **Area of Risk** | **Yes** | **No** | **Details** | **Proposed Plan** |
| 14. | Is there generation of biomedical waste (as described in Bio-Medical Waste Management Rules, 2016) in the grantee? | Yes | | list of biomedical waste produced in the facility. – **List attached at the end of Annexure 2.** | Biomedical waste is sent to PCB authorized third party for disposal |
| 15. | Is there trained staff to handle biomedical waste in the grantee? | Yes | | Biomedical waste handling trained staff available | staff will be trained on biomedical waste policies. |
| 16. | Has the grantee obtained authorization from State Pollution Control Board /Pollution Control Committee? | Yes | | Authorizations obtained | Necessary Authorizations will be taken if required |

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| | | | | | with timely renewals. |
| 17. | Is the biomedical waste segregated at point of generation in the facility and stored in suitable containers? | Yes | | Yellow<br>Red<br>White<br>Blue<br>**List attached at the end of Annexure 2.** | Will follow Biomedical waste management rules |
| 18. | Is the bar code system for the segregated waste in place? | Yes | | System is in place | Will follow bar code system |
| 19. | Is the biomedical waste being sent to an **authorized** common BMW facility? | Yes | | Name and address of CBMWF:<br>1. GJ Multiclave, Hyderabad.<br><br>Distance from facility: 50 Kms<br><br>Frequency and Mode of transport: Daily through Bio medical waste specialized trucks authorized by PCB.<br><br>Who transports? GJ Multiclave, authorized PCB vendor. | |
| 20. | Does the grantee have an in-house BMW treatment facility? | | No | Reason: We send the BMW to a PCB authorized vendor for treatment. | |
| | Is the treatment facility own (individual)? | | No | | |
| | Is the treatment facility a shared facility in an industrial park? | | No | | |
| 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:** Biomedical waste generated in the lab and manufacturing areas is Sterilized and decontaminated in Autoclaves through the Autoclave load pattern and then collected in dedicated non chlorinated bio hazard covers as per the | |

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| | | | | categorization which will be sent to Bio Medical waste storage sheds. Later it will be collected by PCB authorized vendor. Liquid waste will be sent through Kill tank for treatment. | |
| 22. | Is the liquid waste checked for active cells before sending to treatment plant? | Yes | | We send that through Kill tank | |
| 23. | Are necessary waste pre-treatment equipment in place? | Yes | | List of equipment (autoclaves, shredders, incinerators, etc.): Autoclave, shredders are used. They are adhered to norms of SPCB.<br><br>Details of waste pre-treatment:<br>Autoclaves are used to decontaminate and shredders are used to cut the paper waste. | |
| | Do the equipment adhere to prescribed norms by State Pollution Control Board (SPCB)? | Yes | | | |
| 24. | Are chlorinated plastic gloves and bags phased out in the grantee? | Yes | | Only Non-chlorinated bags are used. | Will use only non-chlorinated bags |
| 25. | Are grantee's personnel involved in handling BMW provided with regular training? | Yes | | Frequency: Quarterly<br><br>Trainer: EHS specialist | Training will be provided to the staff handling biomedical waste as per the existing frequency mentioned. |
| 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: Yearly once | |
| 27. | Is a daily register for biomedical waste maintained including accident reporting record? | Yes | | Dedicated register is used for tracking biomedical waste. And also there is a dedicated register to log all the accidents and incidents. | |
| 28. | Are annual reports on BWM submitted to SPCB as per required form (see Bio-Medical Waste Rules 2016)? | Yes | | Annual reports on BMW are submitted to SPCB as per Form IV. | Will ensure that this compliance is done regularly within the |

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| | | | | | timelines. |
| **Hazardous Waste (HW)** | | | | | |
| | **Area of Risk** | **Yes** | **No** | **Details** | **Proposed Plan** |
| 29. | Is there generation of hazardous waste (as per Hazardous Waste Rules, 2016) in the grantee? | Yes | | ETP sludge, boiler soot, expired chemicals, used oil | |
| 30. | Is there trained staff in the facility to identify and handle hazardous waste? | Yes | | Staff from different functions are trained on identification and handling of hazardous waste. | |
| 31. | Does the grantee have authorization from SPCB for hazardous waste? | Yes | | We have the authorization from TSPCB | Timely proper and relevant renewals will be taken if required |
| 32. | Is there a secure location for storage of HW with proper signage? | Yes | | Separate room with 14*14 sqft. is available. Tile flooring, exhaust fan, spill control kit, PPE box are equipped in that room. The Hazardous waste will not be stored more than 90 days . | |
| | Are hazardous waste stored for more than 90 days in the grantee's premises? | | No | | |
| 33. | Is the hazardous being send to an **authorized** disposal facility or user? | Yes | | Name and address of facility: Ramky , Hyderabad | |
| | Is the disposal facility in house? | | No | | |
| | Is the disposal facility external/outsourced? | Yes | | | |
| 34. | Is a register maintained on production and treatment, and a manifest system followed for transport of hazardous waste from the grantee to treatment facility? | Yes | | We have a dedicated online register. | |
| **E-Waste and Batteries** | | | | | |
| | **Area of Risk** | **Yes** | **No** | **Details** | **Proposed Plan** |
| 35. | Does the grantee generate e-waste, produce or manufacture electrical and electronic equipment? | Yes | | E-waste is generated | |

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| 36. | Has the grantee obtained SPCB authorization on e-waste? | Yes | | Sending through buy back policy to vendor. | Company will obtain the authorization from SPCB as and when the need arises. |
| 37. | Does the grantee channelize the e-waste to **authorized** recycling or disposal facility? | | No | | |
| 38. | Does the manufacturing grantee have Extended Producer Responsibility system and EPR-authorization in place? | | No | | |
| 39. | Does the grantee practice reduction in the usage of hazardous substances in the manufacture of electrical and electronic equipment and its parts? | | No | | |
| 40. | Does the grantee provide detailed information on the constituents of the equipment and their components/spares and declaration of conformation to Reduction in Hazardous Substances in the product user documentation? | | No | | |
| 41. | Does the grantee maintain a record of collection, storage, sale and transport of e-waste? | Yes | | A record is maintained | |
| 42. | Does the grantee submit annual reports on e-waste to SPCB? | Yes | | Annual reports on e-waste are submitted to TSPCB. | |
| 43. | Is there accident reporting and records in place? | Yes | | We have a established procedure to report and record the accidents and incidents. | |
| 44. | Are PPEs available to staff? | Yes | | Work specific PPEs are provided to staff and kept in all areas. | The stock status of PPE will be regularly monitored and procurement will be done in time to avoid any situation of stock out as and when needed. |
| 45. | Is the grantee involved in manufacture of batteries? | | No | | |
| 46. | Does the grantee generate battery waste? | Yes | | Sent to vendor as per buy back policy | |

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| 47. | Does the grantee deposit the battery waste to **registered** recycler/dealer/manufacturer/reconditioner/collection center? | Yes | | Name and address of battery waste receiving entity: To the manufacturer of the batteries as per buy back policy | |
| 48. | In case of manufacturing, does the grantee comply to Battery Management Rules 2000 and ensure collection of old batteries? | | No | | |
| **Community Health and Safety and risk mitigation** | | | | | |
| | | **Yes** | **No** | **Details** | **Proposed Plan** |
| 49. | Safety Transportation Management System (for transport Of hazardous material) | Yes | | Only PCB authorized vehicles are used for transportation of hazardous materials. | Will follow the norms of PCB |
| 50. | Emergency preparedness and participation of local authorities and potentially affected communities | Yes | | We involve local Firefighting team in our emergency preparedness | |

| **Other** | | | | | |
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| | **Area of Risk** | **Yes** | **No** | **Details** | **Proposed Plan** |
| 51. | Does the grantee use any radioactive materials (isotopes tracers, radiation equipment, etc)? | | No | No radioactivity will be used for this project. | |
| | Does the grantee have appropriate radioactive material and waste storage and disposal system in place? | | No | No radioactivity will be used for this project. | |
| | Are radioactive warning signs in place? | | No | No radioactivity will be used for this project. | |
| 52. | Is the lab/room air regularly checked for microbial contamination? | Yes | | Regular checking of air is in place for any microbial contamination. | Periodic checks will be done as and when required. |
| 53 | Are there any odor control measures in place? | | No | | |
| 54. | Are fume hoods and exhausts regularly checked and maintained? | Yes | | All the fume hoods and exhausts are regularly checked and maintained. | Periodic checks will be done as and when required. |
| 55. | Does the grantee use DG set > 15 KVA? | Yes | | We have DG sets (08 Nos) of more than 15 KVA capacity. We have the consent order for the DGs. All the emissions from Boilers and DG sets are | DG set emmisions will be regularly monitored as per CPCB rules |
| | 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 | | | |

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| | | | | regularly monitored as per the norms. | |
| 56. | 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 | | Municipal solid waste is collected local municipality . We send plastic waste and paper for recycling. | It will be ensured that segregation rules are followed. This will be maintained and monitored. |
| 57. | Is wastewater treated separately by the grantee? (Liquid waste from laboratory, chemicals, fluids, solvents, medium and cultures, coolants, etc.) | Yes | | **Types of wastewater: Process water and Non process water** **Treatment of wastewater:** Treated in ETP. Process water will be pretreated in Kill tank to kill microbial, bacteria in the water. **Chemical management in wastewater treatment plants:** Chemicals used in ETP are segregated properly to avoid contamination. | These will be periodically checked and maintained to ensure their proper functioning. |
| | Are there sludge management and cut off drains in place for wastewater? | Yes | | Sludge management in place | |
| 58. | Are necessary provisions for noise cancellation in place? | Yes | | Describe: Our DG sets and equipment are provided with acoustic. | |
| 59. | Are there any settlements, water bodies, cultivated land, or any other eco-sensitive areas near the grantee's premises? | | No | | |
| 60. | Are there any buffers, fire vehicle routes in the grantee's premises? | Yes | | Fire vehicles routes are avaliable | |
| **COVID Precautions & Guidelines Implementation** | | | | | |
| 61 | Guidelines of CPCB/SPCB/GoI for Handling, Treatment, and Disposal of COVID Waste Generated is whether being followed? | Yes | | The single use masks and other waste generated are properly disposed as per the norms. | Will follow the norms |
| 62 | SOP on preventive measures to contain spread of COVID-19 issued by ICMR/GoI from time to time is whether being followed? | Yes | | We are adhering to all the regulations issued by ICMR and Govt. Of India. We made a dedicated SOP for COVID-19 preparedness as per the | Will follow the norms |

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| | | | | state and central govt. guidelines. | |

**Biomedical waste segregation containers:**

| Yellow | Red | Blue | White |
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| Experimental Animal Tissues / Organs; Animals used in experiments; Expired / rejected meet; Items contaminated with blood; Body fluids; Bedding Material; Micro Biology & Bio Technology waste; Laboratory Cultures; Human / Animal Cell cultures; Devices used for culture; Pads used in Bio technology process; Human Tissues / Organs | Catheters; Disposable Syringes; VI tubes; Gloves used for handling of Micro Organisms / labs; Tubing's; Blood sample collection containers / bags | Broken / discarded / contaminated Glass; Medicine Vilas / ampoules | Needles; Syringes with fixed needles; Blades; Contaminated sharp objects; Contaminated metal sharp |

**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.**