

## Environmental Health Risk Management Plan (EHRMP)

### Mazumdar Shaw Medical Foundation

**Proposal entitled:** “Development of a novel CoV-trap – a human ACE2 fusion protein nasal spray for COVID-19 therapy”

(i) Brief description of the proposed activity

COVID-19 caused by SARS CoV-2 is an ongoing pandemic with an enormous potential to cause severe health and economic burden across the globe. The COVID-19 virus is transmitted between individuals via respiratory droplets and contact through fomites in the immediate environment around an infected person. The virus gains entry via binding to the human Angiotensin Converting Enzyme 2 ACE2 receptor to establish infection in humans. Biochemical and structural studies suggest the variable receptor binding domain RBD of the spike protein of SARS-CoV-2 to bind with high affinity to ACE2 from humans, ferrets and cats. ACE2 is widely expressed in type II alveolar cells of the lung, heart, liver, kidneys and intestine. Apart from playing a central role in the hormonal response of the cardiorenal system to control blood pressure, it is also found to be a potent receptor for the S-protein of SARS-CoV-2 1,2 . Numerous efforts to develop ACE2 based protein as an antiviral drug for COVID 19 are underway 3,4 . This proposal aims to develop CoV-trap a novel therapeutic fusion protein between the ectodomain of ACE2 and human IgG Fc region as three distinct formulations to trap the virus in circulation in the airway or in blood. Upon expression of the fusion construct in a mammalian host, in presence of Fc, the ACE2 will form an active dimer. The novel fusion protein after formulation optimisation will be characterized using a battery of in vitro binding assays, neutralisation cell-based assays with the pseudovirus, and in vivo challenge model using Golden Syrian Hamster to study the pharmacokinetics and establish efficacy against viral challenge. Binding and neutralisation assays will be done with live virus in BSL3 facility obtained from government approved resources and grown in VeroE6 cells. Once proof of concept is established in murine models, the fusion protein will undergo safety studies and further clinical development as a therapeutic modality in the next phase.

(ii) List of environment related regulatory clearances required for the activity.

Authorizations from PCB are available

#### **Institutional Arrangement**

Area of Risk		Yes	No	Details	Proposed Plan
1.	Is there a designated full-time staff for Environment Health and Safety (EHS) issues?	Yes			It will be managed by the Part of the hospital EHS team
2.	Does the EHS staff handle the following?			1. Occupational Health Centre (OHC) is in place consisting no. of full time qualified doctors.  2. Periodical medical checkup is carried in OHC.  3. Hazardous Waste (HW) generated at site is disposed to CHWTSDF by filling the	
	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			

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

**Mazumdar Shaw Medical Foundation**

				<p>Manifest and record for same in maintained.</p> <p>4. Regular training is carried out to all employee</p> <p>Celebration of Safety Week and world Environment day to create awareness among the employees</p>	
	Environment Management Framework compliance for Innovate in India Project	Yes			Environment Management Framework compliance for Innovate in India Project will be followed
3.	Is there a reporting structure in place regarding EHS issues?	Yes		<p>1.EHS issues are discussed in daily meeting</p> <p>2. Central safety Committee is in place and meeting is carried out in quarterly basis.</p> <p>3. Hierarchy reporting EHS issues is in place Well qualified staff is in place and responsibilities are defined for each and every staff members.</p>	Immediate action will be taken in case of any issues with respect to EHS
4.	Are regular EHS trainings provided to staff?	Yes		<p>1.Training is conducted on monthly basis as per the training needs identified and respective training schedule.</p> <p>2. Training record is maintained</p>	This process will be followed regularly.
5.	Institutional Bio-Safety Committee (IBSC)	Yes		Institutional BioSafety Committee (IBSC) meetings are conducted on quarterly basis and record is maintained	Institutional BioSafety Committee (IBSC) meetings are conducted on quarterly basis.
6.	Ethics Committee (EC)	Yes		Human Ethics committee meeting is conducted as and when required.	Ethics committee meetings will be continued in the future to monitor the ethics parameters involved in the project.
<b>General Occupational Health and Safety</b>					
	<b>Area of Risk</b>	<b>Yes</b>	<b>No</b>	<b>Details</b>	<b>Proposed Plan</b>

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

**Mazumdar Shaw Medical Foundation**

7.	Are there Standard Operating Procedures for accidents, hazards, and other emergencies (chemical spills, heat hazards, fire hazards, radioactive hazards etc.)?	Yes		Standard Operating Procedures are in place. SOPs are reviewed on regular basis.  Training on SOPs is conducted on regular basis. Radioactive material is not used in any process.	1. Standard Operating Procedures are in place and are reviewed on regular basis. 2. Training on SOPs are conducted on regular basis. 3. Next training is planned in the month of December 2020 4. Training evaluation procedure is in place. 5. e-DMS is in place for the SOPs documentations.
8.	Are the following in place?	Yes		1. Chemical spill kits are provided at all identified locations. 2. Eye wash and showers are provided at all required locations 3. First aid kits are provided to each and every department. 4. Register of accidents and dangerous occurrence is in place. 5. Fire extinguishers are provided at required location. 6. Maps are provided at required points.	It is in place in compliance with legal requirement. Functional and general maintenance of all safety equipment are regularly followed. Mock drills and safety training were planned periodically to all the staff members.
	Chemical spill kits	Yes			
	Eye wash	Yes			
	Shower stations	Yes			
	First Aid Kit	Yes			
	Fire Extinguishers	Yes			
	Register of accidents and injuries	Yes			
9.	Are proper signage and storage system in place?	Yes		Proper signage's are in place. MSDS are provided in relevant locations. Emergency numbers are displayed at offices.  Flammable materials are stored on the basis MSDS.	1. Emergency contacts will be updated in change of any key members.  While handling the flammable material suitable PPE's are used.
	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	Yes			

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

**Mazumdar Shaw Medical Foundation**

	fire hazards?				
10.	Are smoke detectors, fire alarms, automatic safety/shut off systems, overflow preventors, etc. in place and regularly maintained?	Yes		1. Servicing of smoke detection system is done on quarterly basis and next due on January 2021. 2. Graphical presentation system is in place at ECC for the fire detection system. 3. Separate manpower is in place for servicing and maintenances of fire detection and alarm system	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		1. Air emission control systems are provided for all DG sets and the Boilers. 2. Regular emission monitoring is done by MOEF and CC approved laboratory. 3. CNG and briquettes are used as fuel for boilers and Furnace oil is getting phased out in coming years.	The SOP will be followed.
12.	Are regular mock drills conducted for emergency preparedness and safety?	Yes		Frequency (type wise): Yearly	1. Mock drills are conducted on regular basis on various scenarios to check the emergency preparedness plan and review the same. 2. On site emergency plan is in place and reviewed on yearly basis next revision is due on January 2021. 4. Report is prepared consisting observations of the observers and the time required for the 4. Short comings of the mock drills are addressed and rectified.
13.	Are staff provided with OHS training?	Yes		Quarterly	1. Training is conducted on monthly basis as per the training schedule. 2. Induction training is provided for new employees. 3. External

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

**Mazumdar Shaw Medical Foundation**

					training is conducted for the EHS staff. 4. Training record is maintained at EHS department	
<b>Biomedical Waste (BMW)</b>						
	<b>Area of Risk</b>	<b>Yes</b>	<b>No</b>	<b>Details</b>	<b>Proposed Plan</b>	
14.	Is there generation of biomedical waste (as described in Bio-Medical Waste Management Rules, 2016) in the grantee?	Yes		a list of biomedical waste produced in the facility  1. Microbiology and 2. Bio medical waste 3. Waste sharp	1. Bio-medical waste is pretreated at site, segregated and labeled according the category of the waste. 2. Biomedical wastes are handed over to appropriate agencies	
15.	Is there trained staff to handle biomedical waste in the grantee?	Yes		Trained staff is in place for handling of biomedical waste	1. Well trained staff is in place for handling of biomedical waste. Training is done on quarterly basis for the staff 2. Medical checkup has been carried out on regular basis for the staff	
16.	Has the grantee obtained authorization from State Pollution Control Board /Pollution Control Committee?	Yes		Has taken the Authorization from PCB as part of the hospital	1. Has taken authorization from PCB 2. Operating the biomedical waste treatment facility as per the condition given by the PCB.	
17.	Is the biomedical waste segregated at point of generation in the facility and stored in suitable containers?	Yes		Yellow	Yes	
				Red	No	
				White	Yes	
				Blue	No	
18.	Is the bar code system for the segregated waste in place?		No		Bar code system will be implemented	

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

**Mazumdar Shaw Medical Foundation**

19.	Is the biomedical waste being sent to an <b>authorized</b> common BMW facility?	Yes		Name and address of CBMWF:  Maridi Bio Industries Pvt Ltd  Distance from facility: 60 km	Biomedical waste will be sent to PCB authorized facility.
20.	Does the grantee have an in-house BMW treatment facility?		No		
	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: Autoclaving	1. Autoclaves, shredders for the pretreatment of the waste. 2. Autoclaves are operated as per the conditions stipulated in consent to operate. 3. SOP is in place for operation and maintenance of the Autoclaves.
22.	Is the liquid waste checked for active cells before sending to treatment plant?	Yes		Liquid waste checked for active cells before sending to treatment plant	1. SOP is in place for checking the active cells in liquid.
23.	Are necessary waste pre-treatment equipment in place?	Yes			1. Autoclaves, shredders for the pretreatment of the waste. 2. Autoclaves are operated as per the conditions stipulated in consent to operate. 3. SOP is in place for operation and maintenance of the Autoclaves.
	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			

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

**Mazumdar Shaw Medical Foundation**

25.	Are grantee's personnel involved in handling BMW provided with regular training?	Yes		Frequency: Quarterly Trainer: : Internal as well as external	1. Well trained staff is in place for handling of biomedical waste. Training is done on quarterly basis for the staff next training is planned in January 2021. 2. Medical checkup has been carried out on regular basis for the staff. 3. SOPs are in place for the operation of incineration and reviewed on regular basis
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: Annually	1. Medical checkup has been carried out on regular basis for the staff. 2. Immunization has been carried out as per the individual schedule for each and every staff involved in handling the BMW.
27.	Is a daily register for biomedical waste maintained including accident reporting record?	Yes			1. Daily register for biomedical waste is in place. 2. Procedure for accident reporting is in place. No accident has been reported till date
28.	Are annual reports on BWM submitted to SPCB as per required form (see Bio-Medical Waste Rules 2016)?	Yes		Annual reports on BMW submitted to PCB as per required form	1. Annual reports on BMW submitted to PCB as per required form before 30th June every year. 2. Record of same is maintained for 5 years.

**Hazardous Waste (HW)**

	<b>Area of Risk</b>	<b>Yes</b>	<b>No</b>	<b>Details</b>	<b>Proposed Plan</b>
--	---------------------	------------	-----------	----------------	----------------------

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

**Mazumdar Shaw Medical Foundation**

29.	Is there generation of hazardous waste (as per Hazardous Waste Rules, 2016) in the grantee?		No	Hazardous waste is not generated	If Hazardous waste is generated it will sent to authorized facility
30.	Is there trained staff in the facility to identify and handle hazardous waste?	Yes			Required training will be provided to staff from time to time
31.	Does the grantee have authorization from SPCB for hazardous waste?		No	Hazardous waste is not generated	Authorizations will be obtained if required
32.	Is there a secure location for storage of HW with proper signage?		No	Hazardous waste is not generated	If Hazardous waste is generated it will be stored in secured location with proper signage
	Are hazardous waste stored for more than 90 days in the grantee's premises?		No		
33.	Is the hazardous being send to an <b>authorized</b> disposal facility or user?		No	Not generated	If Hazardous waste is generated it will sent to authorized facility
	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?		No	Hazardous waste is not generated	Register will be maintained if hazardous waste is generated

**E-Waste and Batteries**

	<b>Area of Risk</b>	<b>Yes</b>	<b>No</b>	<b>Details</b>	<b>Proposed Plan</b>
35.	Does the grantee generate e-waste, produce or manufacture electrical and electronic equipment?	yes		E- waste is generated	1. Will dispose the e-waste as per the rules. 2. Will submit the Annual returns for the e waste. 3. Will maintain the record for the e-waste
36.	Has the grantee obtained SPCB authorization on e-waste?	yes		Authorization is obtained for the e waste	1. Received the e waste Authorization from PCB.

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

**Mazumdar Shaw Medical Foundation**

					2. Will dispose the e-waste to authorized recycler
37.	Does the grantee channelize the e-waste to <b>authorized</b> recycling or disposal facility?	yes			1. Will dispose the e-waste to authorized recycler. 2. List of PCB authorized recyclers is available
38.	Does the manufacturing grantee have Extended Producer Responsibility system and EPR-authorization in place?		No	No manufacturing in our activity	
39.	Does the grantee practice reduction in the usage of hazardous substances in the manufacture of electrical and electronic equipment and its parts?		No	No manufacturing in our activity	
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	No manufacturing in our activity	
41.	Does the grantee maintain a record of collection, storage, sale and transport of e-waste?	Yes		Through the hospital	1. Will be maintaining the record of e waste.
42.	Does the grantee submit annual reports on e-waste to SPCB?	Yes		Through the hospital	
43.	Is there accident reporting and records in place?	Yes		Accident reporting form as per the rule is in place.	1. Record is being maintained in the prescribed format.
44.	Are PPEs available to staff?	Yes		PPEs available to staff	1. Required PPEs are available for the staff. 2.PPE Inventory and records are maintained
45.	Is the grantee involved in manufacture of batteries?		No	Doesn't involve in manufacture of batteries.	
46.	Does the grantee generate battery waste?	Yes		Generates battery waste.	1. Batteries are purchased on the buyback basis and return back to vendor after use

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

**Mazumdar Shaw Medical Foundation**

47.	Does the grantee deposit the battery waste to <b>registered</b> recycler/dealer/manufacturer/rec conditioner/collection center?	Yes		List of authorized recycler is available	1. Batteries are purchased on the buyback basis and return back to vendor after use. 2. Records are maintained with the hospital
48.	In case of manufacturing, does the grantee comply to Battery Management Rules 2000 and ensure collection of old batteries?		No	No manufacturing in our activity	
<b>Community Health and Safety and risk mitigation</b>					
		<b>Yes</b>	<b>No</b>	<b>Details</b>	<b>Proposed Plan</b>
49.	Safety Transportation Management System (for transport Of hazardous material)		No		If hazardous waste generated this system will be followed
50.	Emergency preparedness and participation of local authorities and potentially affected communities	Yes		On site emergency plan is in place and same reviewed on regular basis.	1. On site emergency plan is in place 2. Regular mock drills are conducted considering various scenarios and short comings are addressed. 3. Well trained staff is present 24x7. 4. Fire alarm, Fire Detection and Public address system is in place. 5. SOPs are in place and reviewed on regular basis.
<b>Other</b>					
	<b>Area of Risk</b>	<b>Yes</b>	<b>No</b>	<b>Details</b>	<b>Proposed Plan</b>
51.	Does the grantee use any radioactive materials (isotopes tracers, radiation equipment, etc)?		No	Radioactive materials is not used for this project	
	Does the grantee have appropriate radioactive material and waste storage and disposal system in place?		No	Radioactive materials is not used for this project	

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

**Mazumdar Shaw Medical Foundation**

	Are radioactive warning signs in place?		No	Radioactive materials is not used for this project	
52.	Is the lab/room air regularly checked for microbial contamination?	Yes		Room air regularly checked for microbial contamination	1. SOPs are in place for the monitoring and reviewed on regular basis. 2. Records are maintained for the monitoring.
53.	Are there any odor control measures in place?		No		
54.	Are fume hoods and exhausts regularly checked and maintained?	Yes			1. Fume hoods are provided in the lab. 2. Filters of fume hoods are changed on regular basis.
55.	Does the grantee use DG set > 15 KVA?	Yes			1. DG sets are in place 2. Regular monitoring is done through the hospital
	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			
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		Has proper disposal process for solid and plastic waste in compliance to Solid Waste Management Rules, 2016 and Plastic Waste Management Rules, 2016	
57.	Is wastewater treated separately by the grantee? (Liquid waste from laboratory, chemicals, fluids, solvents, medium and cultures, coolants, etc.)	Yes		Treatment of wastewater is done through the hospital	
	Are there sludge management and cut off drains in place for wastewater?		No		System will be implemented if required
58.	Are necessary provisions for noise cancellation in place?	Yes		Acoustic enclosures are provided to all the DG sets. Maintenance schedule is in place for all the equipment's. Regular noise monitoring is done	
59.	Are there any settlements, water bodies, cultivated land, or any other eco-sensitive areas near the grantee's premises?		No		

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

**Mazumdar Shaw Medical Foundation**

60.	Are there any buffers, fire vehicle routes in the grantee's premises?	Yes		Fire Vehicle routes are provided	
<b>COVID Precautions &amp; Guidelines Implementation</b>					
61	Guidelines of CPCB/SPCB/GoI for Handling, Treatment, and Disposal of COVID Waste Generated is whether being followed?	Yes		Strictly following the Guidelines of CPCB/SPCB/GoI for Handling, Treatment, and Disposal of COVID Waste Generated is whether being followed	
62	SOP on preventive measures to contain spread of COVID-19 issued by ICMR/GoI from time to time is whether being followed?	Yes		SOP on preventive measures to contain spread of COVID-19 issued by ICMR/GoI from time to time is being followed. Separate Guidelines and notices are in place	

**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.**