#### **Serum Institute of India Private Limited**

**Proposal entitled**: A Multicentre, Phase III, Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Efficacy of Recombinant BCG VPM1002 in Reducing Infection Incidence and Disease Severity of SARS-COV-2/COVID-19 Among High-Risk Subjects

#### 1. Institutional Arrangements

(i) Brief description of the proposed activity

Phase III, Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Duration of Acute Respiratory Symptoms Among Exposed High-Risk Population During Covid-19 Pandemic by Enhanced Trained Immune Response Through VPM1002 RBCG Vaccine

(ii) List of environment related regulatory clearances required for the activity Consent to Establish and operate from MPCB.

#### **Institutional Arrangement**

	The state of the s						
Are	a of Risk	Yes	No	Details	Proposed Plan		
1.	Is there a designated full-time staff for Environment Health and Safety (EHS) issues?	Yes		EHS Team is in place and working. Five no. of well qualified and vast experienced persons in safety team.	place and will be working according to the		
2.	Does the EHS staff handle the following?			Any other:	1. Occupational		
	Occupational Health and Safety	Yes		Celebration of	Health Centre		
		Yes		Safety Week and	(OHC) is in place		
	procedures	Yes		world Environment day to create	consisting Tive		
		Yes		day to create awareness among the employees	no. of full time qualified doctors.		
	EHS trainings for staff	Yes		the employees			

	Environment Management Framework compliance for Innovate in India Project	Yes	2. Pre- employment and periodical medical checkup wills be carried in OHC. Annual medical check started from October 2020 is in progress.  3. Hazardous Waste (HW) generated at site will be disposed to CHWTSDF by filling the Manifest and record for same in maintained.  4.HW disposal is planned in December 2020  5. Regular training will be carried out to all the employees as per the training schedule.  6. SOP for accident reporting is in place and will
			is in place and will be reviewed on regular basis.
3.	Is there a reporting structure in place regarding EHS issues?	Yes	Describe: 1.EHS issues will issues are discussed be discussed in daily meeting 2. Central safety Committee is in place and meeting is carried out in quarterly basis.  3. Hierarchy reporting EHS issues 2. Central safety committee meeting is planned in month of December 2020 as follow.  3. Well qualified staff is in place Occupier and

			Director HRD  Sr. Manager -EHS  Manager -EHS  Asst. Manager EHS  Executive EHS  Operating staff	responsibilities defined for each and every staff members will be taken up by them.
4.	Are regular EHS trainings provided to staff?	Yes	Frequency: Monthly	1. Training will be conducted on monthly basis as per the training needs identified and respective training schedule.  2. Induction training will be provided for new employees.  3. External training will be conducted for the EHS staff.  4. Training record will be maintained at EHS department.
5.	Institutional Bio-Safety Committee (IBSC)	Yes	Institutional Bio Safety Committe (IBSC) meetings are conducted or quarterly basis.	Institutional Bio- Safety Committee (IBSC) meetings will be conducted on quarterly basis.
6.	Ethics Committee (EC)	Yes	The composition of the Ethics Committed will be as per the ICH and NDCT 2019 guidelines.	Ethics committee meetings will be continued in the future to monitor

					the ethics
					parameters
					involved in the
					project.
	General Occupational H	ealth	and	Safety	project.
	Area of Risk	Yes		Details	Proposed Plan
			110		l Toposca Tian
7.	Are there Standard Operating Procedures			Standard Operating	1. Standard
	for accidents, Hazards, and other				Operating
	emergencies (chemical spills, heat	Yes		place.	Procedures will be
	hazards, fire hazards, radioactive hazards			SOPs are reviewed on	
	etc.)?				reviewed on
				Training on SOPs is	
				conducted on regular	
				basis.	SOPs will be
					conducted on
				in not used in any	
				process.	3. Next training is
					planned in the
					month of
					December 2020
					4. Training
					evaluation
					procedure is in
					place will be
					followed.
					5. e-DMS in place
					for the SOPs
					documentations
					will be adhered
					and followed.
8.	Are the following in place?			1. Chemical spill kits	
	Chemical spill kits	Yes		are provided at all	-
				*	general
	Eye wash	Yes			maintenance of all
	Shower stations	Yes		showers are provided	safety equipment
	Shower stations	168		<u> </u>	lare regularly
	First Aid Kit	Yes		locations	followed. Mock
				3. First aid kits are	drills and safety
	Fire Extinguishers	Yes		provided to each and	· · · · · · · · · · · · · · · · · · ·
	Register of accidents and injuries	Yes		every department.	planned
	register of accidents and injuries	1 es		4. Register of	periodically to all
					the staff members.
L		L		dangerous occurrence	

is in place.
5. Fire extinguishers
are provided at
required location.
6. Training on
Handling and
operation of fire
extinguishers are
conducted on regular
basis to all the
employees.
7. Register of
accidents and
dangerous occurrence
is in place in
compliance with legal
requirement.

9.	Are proper signage and storage system in place?	Yes	T T T T
		<b>T</b> 7	signage's are in place and stock will be
	Display of Material Safety Data Sheet (MSDS) where relevant	Yes	place. maintained as per the
			—MSDS are guidelines for Environment
		Yes	provided in Health and Safety (EHS)
	procedures (Person to Contact, Doctor,		relevant enacted by the legislature.
	Ambulance, Fire Emergency, Police)		locations.
	displayed in all critical		Emergency
	Places		numbers are
		Yes	displayed at gate
	storage, hazardous areas, etc.)		
		Yes	and emergency
	stored to prevent fire hazards?		control center.
			Flammable
			materials are
			stored on the
			basis MSDS.
10.	Are smoke detectors, fire alarms, automatic	Yes	List: Attached 1
	safety/shutoff systems, overflow		. Servicing of Smoke detectors, fire
	preventers, etc. in place and regularly		smoke detectionalarms, automatic
	maintained?		system is donesafety/shut off systems will
			on quarterly be regularly maintained
			basis and next
			due on January
			2021.
			2. Graphical

		1	
			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
4.4			system
11.	Are there control measures for VOC, air	Yes	
	emissions, high operating temperatures,		1. Air emission Regular emission
	pathogens/vectors etc. in place?		control systems monitoring will be done by
			are provided for MOEF and CC approved
			all DG sets and laboratory.
			the Boilers.
			2. Regular
			emission
			monitoring is
			done by MOEF
			and CC
			approved
			laboratory.
			3. CNG and
			briquettes are
			used as fuel for
			some of the
			boilers and
			Furnace oil is
			getting phased
			out in coming
12	Ano monitor monte della accidente d	<b>T</b> 7	years.
12.	Are regular mock drills conducted	Yes	
	for emergency preparedness and		(type wise): conducted on regular basis
	safety?		Quarterly on various scenarios to
			check the emergency
			preparedness plan and
			review the same.
			2. On site emergency plan
			1 1
			in place will be reviewed
			on yearly basis next
			revision is due on January

10				2021. 4. Report will be prepared consisting observations of the observers and the time required for the 4. Short comings of the mock drills will be addressed and rectified.
13.	Are staff provided with OHS training?	Yes	Describe: Monthly	<ol> <li>Training will be conducted on monthly basis as per the training schedule.</li> <li>Induction training will be provided for new employees.</li> <li>External training will be conducted for the EHS staff.</li> <li>Training record will be maintained at EHS department.</li> </ol>
	Biome	dical `	Waste (BMW)	
	Area of Risk		o Details	Proposed Plan
14.	Is there generation of biomedical waste (as described in Bio-Medical Waste Management Rules, 2016) in the grantee?	Yes	provide a list of biomedical waste produced in the facility-1. Animal waste 2. Microbiolog y and Biotechnology waste 3. Waste sharp  If No, provide list of all wast	<ul><li>3. Bio medical waste will be treated in house facility through Incineration.</li><li>4. Emission form incinerator stack will be amonitored continuously.</li></ul>

			approved third party. 6. Annual returns will be submitted to MPCB.
15.	Is there trained staff to handle biomedical waste in the grantee?	Yes	Trained staff is Regular training and in place for review will be done for the handling of staff involved in this. biomedical waste  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. Bio medical waste is disposed usig our own treatment facility i.e. Incineration plant  4. SOPs are in place for the operation of incineration and reviewed on regular basis.
16.	Has the grantee obtained authorization from State Pollution Control Board /Pollution Control Committee?	Yes	Grantee has taken the Necessary Authorizations

			T:
			Authorization will be taken if required
			from MPCB with timely renewals.
			copy of the same
			is enclosed as
			annexure.
			1. Grantee has
			taken
			authorization
			from MPCB
			same in valid up
			to March 2021.
			2. Grantee is
			operating the
			biomedical
			waste treatment
			facility as per the
			condition given
			by the MPCB.
			3. Regular
			monitoring of
			incinerator stack
			has been carried
			through MOEF
			and CC
			approved third
			party and next
			monitoring is
			planned in last
			week of
			November 2020.
17.	Is the biomedical waste segregated at point	Yes	Yello Yes This is an ongoing process
	of generation in the facility and stored in		which will be followed
	suitable containers?		Red No throughout the Project.
	Saluoto Collumbio.		White Yes
			Blue No
18.	Is the bar code system for the segregated	Yes	Bar coding Will ensure a proper
	waste in place?		system is in system is in place adhering
			place and to BMW Act during the
			records areProject.
			maintained on
			regular basis.
			1. Bio-medical
			waste is
			pretreated at site,

segregated and
labeled
according the
category of the
waste.
2. Bar coding
system is in
place and
records are
maintained on
regular basis.
3. Bio medical
waste is treated
in house facility
through
Incineration.
4. Grantee has
taken
authorization
from MPCB
same in valid up
to March 2021.

19.	Is the biomedical waste being sent to ar	No No	Name and	1. Grantee has taken
	authorized common BMW facility?		address of	authorization from
			CBMWF:	MPCB same is valid
				up to March 2021.
			Distance from	2. Bio medical waste
			facility:	is treated in house
				facility through
			Frequency	Incineration.
			and Mode of	3. Bar coding system
			transport:	is in place and records
				are maintained on
			Who	regular basis.
			transports?	4. Regular monitoring
				of incinerator stack
				has been carried
				through MOEF and
				CC approved third
				party and next
				monitoring is planned
				in last week of

				November 2020.
20.	Does the grantee have an in-house BMW treatment facility?  Is the treatment facility own (individual)?  Is the treatment facility a shared facility in an industrial park?	Yes	NI.	Reason: Capacity  Of CBWM reviewed efficiently facility is limited. Authorization: Authorization authorization from taken from MPCB same is valid up to March 2021. 2. Bio medical waste is treated in house nearest facility through CBWM from facility:13.4 Km is in place and records are maintained on Types of regular basis.  4. Regular monitoring of incinerator stack has been carried through MOEF and CC approved third party and next monitoring is planned in last week of November 2020.
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 SOP in place for treatment: operation and Mutoclaving maintenance of the 1. Autoclaves, Autoclaves will be shredders for the followed. pretreatment of Compliance Calendar the west. shall be maintained. 2. Autoclaves are operated as per

			the conditions stipulated in consent to operate.	
22.	Is the liquid waste checked for active cells before sending to treatment plant?	Yes	checked for active cells	SOP in place for checking the active cells in liquid will be followed throughout the project.
23.	Are necessary waste pre-treatment equipment in place?	Yes	List of equipment (autoclaves,	Regular monitoring shall be done.
	Do the equipment adhere to prescribed norms by State Pollution Control Board (SPCB)?	Yes	shredders, incinerators, etc.):	
			Details of waste pretreatment:  1. Autoclaves, shredders for the pretreatment of the west.  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.	
24.	Are chlorinated plastic gloves and bags phased out in the grantee?	Yes	Chlorinated plastic gloves and bags phased out	
25.	Are grantee's personnel involved in handling BMW provided with regular training?	Yes	Frequency: Quarterly	This will be a regular process during the project.

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
regular vasis

26.	Are medical examination provided to	Yes	Frequency of medical 1. Medical checkup
	personnel involved in BMW waste		examination: will be carried out on
	handling and are they provided with		Annually regular basis for the
	relevant immunization like Hepatitis B		staff.
	and Tetanus?		2. Immunization will
			be carried out as per
			the individual
			schedule for each and
			every staff involved
			in handling the
			BMW.
27.	Is a daily register for biomedical	Yes	Procedure for accident 1. Daily register for
	waste maintained including		reporting is in place.biomedical waste in
accident reporting record?		No accident has been place will be	
			reported till date. maintained.
			2. Procedure for
			accident reporting in

28.	Are annual reports on BMW submitted to SPCB as per required form (see Bio-Medical Waste Rules 2016)?	Yes			
				years.	
	Hazardous V			•	
	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		produced in the facility  1.ETP sludge  2. Date expired, discarded off specification of chemicals.  3.Used Oil  If No, provide a list of all waste produced in the facility.	will be disposed as per Hazardous Waste Rules, 2016 2. Manifest system in place and records will be maintained for the same.  3. Waste generation records will be maintained on monthly basis in Form -3
30.	Is there trained staff in the facility to identify and handle hazardous waste?	Yes			1. Hazardous waste will be disposed as per as per Hazardous Waste Rules, 2016 2. Manifest system in place and records will be maintained for the same. 3. Well trained staff is

31.	Does the grantee have authorization from SPCB for hazardous waste?	Yes		Grantee has taken authorization from MPCB.	in place for handling of hazardous waste.  Hazardous waste will be disposed as per as per Hazardous Waste Rules, 2016. Proper and necessary approvals will be taken within timelines.
32.	Is there a secure location for storage of HW with proper signage?  Are hazardous waste stored for more than 90 days in the grantee's premises?		No No	Describe how each item is stored – platforms, distances from critical installations/move ment areas, spill collectors, gas escape facility, etc. Waste disposal is planned in the month of November 2020.	Hazardous waste generation quantity is
33.	Is the hazardous being send to an authorized disposal facility or user?  Is the disposal facility in house?  Is the disposal facility external/outsourced?		No	of facility: Maharashtra Enviro Power Limited (MEPL)	1.Hazardous waste will be disposed as per as per Hazardous Waste Rules, 2016 2. Manifest system in place and records will be maintained for the same.
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		followed for transport of hazardous waste.	1.Hazardous waste will be disposed as per as per Hazardous Waste Rules, 2016 2. Manifest system in place and records will be maintained for the same.

	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		waste	1. Grantee will dispose the e- waste as per the rules. 2. Grantee will submit the Annual returns for the e waste. 3.Grantee will maintain the record for the e-waste		
36	Has the grantee obtained SPCB authorization on e-Waste?	Yes			<ol> <li>Grantee has received the e waste Authorization from MPCB.</li> <li>Grantee will dispose the e-waste to authorized recycler</li> </ol>		
37	Does the grantee channelize the e-waste to authorized recycling or disposal facility?	Yes		Name and addres s of dispos al facility / recycle r: In- house or outsour ced Facility:	1. Grantee will dispose the e-waste to authorized recycler. 2. List of MPCB authorized recyclers is available with grantee.		
38	Does the manufacturing grantee have Extended Producer Responsibility system and EPR-		No	Describe:			
39	authorization in place?  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		Records are 1. Grantee will be maintained maintaining the record of e waste.  2. Grantee will maintain the record in Form -2 as specified in the e waste Rules.
42	Does the grantee submit annual reports on e-waste to SPCB?	Yes		Submitted on annually submit the annual as perreport in Form -3 and prescribed submission is planned timelines. on or before 30 <sup>th</sup> June 2021.  2. Grantee will maintain the record in Form -2 as specified in the e waste Rules.
43.	Is there accident reporting and records in place?	Yes		Accident 1. Record is being reporting maintained in the form as perprescribed format. the rule is in place.
44.	Are PPEs available to staff?	Yes		PPEs 1. Required PPEs will available tobe made available for staff. SOPthe staff. for use of 2.PPE Inventory and PPEs inrecords will be place. maintained by grantee.  3. Training on use PPE will be conducted on regular basis.
45.	Is the grantee involved in manufacture of batteries?	f	No	Grantee Will implement doesn't appropriate measure involve inas per rules and manufactur regulations if needed e ofin future.

				batteries.	
46.	Does the grantee generate battery waste?	Yes		Grantee generates battery waste.	<ol> <li>Batteries are purchased on the buyback basis and return back to vendor after use</li> </ol>
47.	Does the grantee deposit the battery waste to registered recycler/ dealer/ manufacturer/ reconditioned/ collection center?			waste receivin g entity:	1. Batteries will be purchased on the buyback basis and returned back to vendor after use. 2. List of authorized recycler is available with grantee. 3. Records for the same will be maintained.
48.	In case of manufacturing, does the grantee comply to Battery Management Rules 2000 and ensure collection of old batteries?	;	No		Will implement appropriate measures as per rules and regulations if needed in future.
	Community Health and Safety	and	risk ı	nitigation	
		Yes			Proposed Plan
49.	Safety Transportation Management System (for transport of hazardous material)		No	the Hazardous	
50.	Emergency preparedness and participation of local authorities and potentially affected communities	Yes		On site emergency plan is in	1.On site emergency plan in place whose next revision is due in January 2021

	same	2. Regular mock
	reviewed	drills will be
	on regulai	conducted
	basis.	considering various
		scenarios and short
		comings will be
		addressed.
		3. Well trained staff
		will be made
		available 24x7.
		4. Fire alarm, Fire
		Detection and Public
		address system in
		place will be
		maintained.
		5. SOPs are in place
		will be reviewed on
		regular basis.

	Other						
	Area of Risk	Yes	No	Details		Proposed Plan	
51.	Does the grantee use any radioactive materials (isotopes, tracers, radiation equipment, etc.)?		No				
	Does the grantee have appropriate radioactive material and waste storage and disposal system in place?		No				
	Are radioactive warning signs in place?		No				
52.	Is the lab/room air regularly checked for microbial contamination?	Yes		Room air checked fo contaminati	or microbial ion.	<ol> <li>SOPs are in monitoring and regular basis.</li> <li>Records maintained for an annual part of the regular area.</li> </ol>	reviewed on will be
53	Are there any odor control measures in place?		No			Preventive me with maintenan be put in place required.	ice plan will
54.	Are fume hoods and exhausts regularly checked and maintained?	Yes			led in QC	Filters of fumo be changed and on regular basis	d maintained

55.	Does the grantee use DG set > 15 KVA?	Yes	DG sets are in place
	Does the grantee have consent for DO > 15 KVA?	Yes	—and listed in Consent to 1. Regular monitoring will Operate. Regular be done through MOEF and
	Are emissions from boilers and DG sets regularly monitored to be within the prescribed norms?	Yes	monitoring is done CC approved third party and through MOEF and CC emissions are in the limit. approved third party 2. Next monitoring is and emissions are in the planned in February 2021. limit.  3. CNG and Biomass briquettes will be used as fuel for boilers.
	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	Describe Grantee has proper disposal process for solid and plastic waste in compliance to Solid Waste Management Rules, 2016 and Plastic Waste Management Rules, 2016 and 2016
57.	Is wastewater treated separately by the grantee? (Liquid waste from laboratory, chemicals, fluids, solvents, medium and cultures, coolants, etc.)	Yes	Types of wastewater: Treatment of checks and balances.  wastewater: Waste water is treated in well-established ETP consisting primary, secondary and tertiary treatment units. Chemical management in wastewater treatment plants: 1.Chemicals stored in separate storage shed.

				2.Jar test is	
				conducted for the	
				calculation of	
				required dose of	
				chemicals	
				3. SOPs are in place	
				for the operation of	
				ETP plant.	
				4. Required PPE is	
				provided to ETP	
				staff.	
	Are there sludge management and cut	Yes		1. Decanter is provided	Will ensure that they are
	off drains in place for wastewater?			for the separation of	maintained throughout to
					treat the wastewater.
				2. Sludge is disposed to	
				CHWTSDF by filling	
				the Manifest system.	
				3. Records are	
				maintained and annual	
				returns are Submitted	
				on regular basis to	
				MPCB.	
				4. Grantee has taken the	
				membership from	
				CHWTSDF.	
58.	Are necessary provisions for noise	Ves			1. Regular noise monitoring
	cancellation in place?	100		enclosures are	will be done through MOFF
	•			provided to all the DG	and CC approved third
				sets. Maintenance	and CC approved unitu
				schedule is in place for	party.
					2. Monitoring will be done
				Regular noise	on monthly basis and same
				monitoring is done	is planned in next month.
				CC approved third	3. Maintenance schedule shall be adhered to for the
					all the equipment at site.
				for boiler operators	4. Air muffs are provided
				for boiler operators. Caution Signage's are	
				displayed at the high	5. Caution Signage's are
					0 0
					displayed at the high noise
<u></u>	A (1)		<b>76.</b> T		areas.
59.	Are there any settlements, water		No		
	bodies, cultivated land, or any other				
	eco-sensitive areas near the grantee's				
	premises?				

#### **Serum Institute of India Private Limited**

60.	routes in the grantee's premises?		1. Grantee has fire Will ensure that the water reservoir of 1500 premise is well equipped KL capacity. with these essential 2. Grantee has mini fire services. tender of 600 lit capacity.  3. Fire vehicles routes are provided I premises.			
COVID Precautions & Guidelines Implementation						
61	Guidelines of CPCB/SPCB/GoI for Handling, Treatment, and Disposal of COVID Waste Generated is whether being followed	Yes	Grantee is strictly We will continue to comply following the with the latest Govt. Guidelines of guidelines 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 Employees are trained on measures to contain COVID - 19 measures spread of COVID-19 regularly. issued by ICMR/GoI from time to time is being followed.  Grantee has prepared separate SOP and same is updated on regular basis.			

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.