National Institute of Animal Biotechnology

Proposal entitled: Complete solution for molecular diagnosis of COVID19 multiplex assay along with screening for other related respiratory diseases

(i) Brief description of the proposed activity

The activity at NIAB involves validation of the material transport medium (MTM) and the nucleic acid purification kits developed and manufactured by Huwel Lifesciences. For this, the following activities will be carried out

- a) Bacteria or viruses, which are handled under biosafety level 2 shall be mixed with MTM and nucleic acids (genomics, plasmid) will be extracted at various times.
- b) The efficiency of nucleic acid extraction and its use for further down-stream applications shall be evaluated.
- List of environment related regulatory clearances required for the activity. (ii) а

a) Institutional biosafety commit	tee (IBSC)
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		Insti	tutio	nal	
	Arrangement			L	
	of Risk	Yes		Details	Proposed Plan
1.	Is there a designated full- time staff for Environment Health and Safety (EHS) issues?		Х		A committee of research scientists oversees EHS activities and this committee will be consulted. Will employ an EHS Consultant as and when required during the Project
					Project.
2.	Does the EHS staff handle the following?			the internal safety committee serves to oversee the activities	The internal and institutional biosafety
	Occupational Health and Safety		Х		committees are tasked
	Waste Management		X	-	with waste management,
	List of consents and regulatory clearances		X	-	regulatory clearances, recording accidents and
	Record keeping of accidents and procedures		Х		other procedures, training of students & research
	EHS trainings for staff		Х		personnel as well as other
	Environment Management Framework compliance		X		compliances We will comply to
	for Innovate in India Project				Environment Management Framework compliance for Innovate in India Project

3.	Is there a reporting structure in place regarding EHS issues?	X		Describe: Yes, in the order of individual laboratory heads to internal safety committee to institutional biosafety committee to academic/research head to the highest competent authority	A proper reporting structure will always be ensured during the course of project.
4.	Are regular EHS trainings provided to staff?	X		Frequency: Once a year	Training will be provided as and when required to all the existing as well as newly recruited staffs
5.	Institutional Bio-Safety Committee (IBSC)	X		Meets twice a year	
6.	Ethics Committee (EC)	X*		Yes for animal ethics	*No for human ethics, but in the process of registration. Project will begin only after getting approval from Ethics Committee (EC). Periodic review and meeting will be scheduled.
	General Occupationa	al He	alth a	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.)?	X		Laboratory safety manual consisting of safety procedures and action against emergencies available	The existing SOP will be followed. All the new joining and existing staff will be trained time to time for handling any such situation.
8.	Are the following in place?	v		Eye wash & shower stations in	Facilities will be upgraded
	Chemical spill kits Eye wash Shower stations	X X X		each lab module; first aid kit and registers in centralized place; fire extinguishers on each	as the activities increase and proper records will be maintained.
	First Aid Kit Fire Extinguishers	X X		floor; incidence registry maintained with campus	
	Register of accidents / injuries	X		security	
9.	Are proper signage and storage system in place?	X		Display, signage, storage done as required	Facilities will be upgraded as the activities increase.
	Display of Material Safety Data Sheet (MSDS) where relevant	X		All MSDS maintained by the store/purchase department; signage posted where required	For storage of flammable materials and solvents, systems will be upgraded
	Display of emergency numbers and procedures (Person to Contact, Doctor, Ambulance, Fire Emergency, Police)	X		Displayed in prominent places, including lifts and main passageways	as and when the need arises.

	displayed in all critical places				
	aispidyee in an orneal places				
	Signage across the	X		Displayed	
	facility (labs, storage,				
	hazardous areas, etc.)				
	Are flammable materials	Х		Stored in clearly identified	
	appropriately stored to prevent fire hazards?			areas	
10.	Are smoke detectors, fire alarms,	Х		List: Fire alarms, automatic	Facilities will be
	automatic safety/shut off			systems, overflow preventors in	maintained and upgraded as the activities increase.
	systems, overflow preventors, etc. in place and regularly			place, and regularly monitored and maintained by dedicated	The current safety systems
	maintained?			staff	will be maintained on
					regular basis.
11.	Are there control measures for	Х			Existing control measures
	VOC, air emissions, high			hoods, biosafety cabinets,	for air emissions, high
	operating temperatures,			exhaust cabinets	operating temperatures, pathogens/vectors etc.,
	pathogens/vectors etc. in place?				pathogens/vectors etc., will be continuously
					monitored to maintain the
					safety parameters.
12.	Are regular mock drills	Χ		Frequency (type wise): annual	Will ensure that this
	conducted for emergency			drills for chemical, biological,	process will be regularly
	preparedness and safety?			radiological and fire safety	followed as per schedule
13.	Are staff provided with OHS	Х		Describe: classroom training	Will ensure that this
	training?			once a year; security staff	process will be regularly
				provided other periodic training	followed.
				on fire safety, snake bite prevention, other emergencies	
		Bio	medi	cal Waste (BMW)	
	Area of Risk	1	No	· · · · · · · · · · · · · · · · · · ·	Proposed Plan
14.	Is there generation of	Х			BMW generated will be
	biomedical waste (as described			biomedical waste produced in	treated adhering to Bio-
	in Bio-Medical Waste			the facility	Medical Waste
	Management Rules, 2016) in				Management Rules, 2016
	the grantee?			• Microbiology and	
				biotechnology waste – from prokaryotic & eukaryotic cell	
				culture, bacteria & viruses,	
				plasmids & recombinant	
				DNA – both solid and liquid	
				• Experimental animal waste –	
				tissues, dead bodies,	
				biological fluids – both solid	

				and liquid If No, provi		
				facility.	oduced in the	
15.	Is there trained staff to handle biomedical waste in the grantee?	Х		All research plaboratory or supervisors a	•	Will ensure that this process will be regularly followed.
16.	Has the grantee obtained authorization from State Pollution Control Board /Pollution Control Committee?	X		Authorization	n from SPCB	Authorizations will be renewed from time to time.
17.	Is the biomedical waste segregated at point of generation in the facility and stored in suitable containers?			Yellow Red White Blue	X X X	Very little blue waste generated; white containers will be used for the same.
18.	Is the bar code system for the segregated waste in place?		X			Currently only following segregation based on color coding; the waste collector has barcoding system in place, which will be extended to the institute in the immediate future
19.	Is the biomedical waste being sent to an authorized common BMW facility?	X		GJ Multiclac	and when rts?	Will continue this process and agreement with authorized facility will be renewed from time to time.
20.	Does the grantee have an in-house BMW treatment facility?	X		Reason: As SPCB	per requirement of	In house autoclaving will be followed. The BMW will be carried and treated
	Is the treatment facility own (individual)?	Х		Authorizatio	on: SPCB	by the in house authorized people and we will keep a

	Is the treatment facility a shared facility in an industrial park?	X	Distance of nearest CBWM from facility: Not applicable Types of treatment: Most of the microbiology and biotechnology waste is autoclaved before disposal; all of the liquid waste is treated with hypochlorite before disposal into drain; certain liquid material is disposed into red/hot drains, which are connected to an industrial boiler, before disposal.	record of these.
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?		Types of treatment: Most of	Will continue this process as per BWM rules 2016.
22.	Is the liquid waste checked for active cells before sending to treatment plant?	X	No transportation is involved, and liquid waste is directly dumped in designated sinks. Most of the microbiology and biotechnology waste is autoclaved before disposal; all of the liquid waste is treated with hypochlorite before disposal into drain; certain liquid material is disposed into red/hot drains, which are connected to an industrial boiler, before disposal	Routine checks will be done if required.
23.	Are necessary waste pre- treatment equipment in place?	X		Regular monitoring will be done.
	Do the equipment adhere to prescribed norms by State Pollution Control Board (SPCB)?	X	Details of waste pre- treatment: as described above	
24.	Are chlorinated plastic gloves and bags phased out in the	X	Plastic gloves have never been used, and chlorinated plastic	Will continue the same process

	grantee?			bags have been phased out.	
25.	Are grantee's personnel involved in handling BMW provided with regular training?	X		Frequency: Once a year Trainer: Internal safety committee	This will be a regular process during the project.
26.	Are medical examination provided to personnel involved in BMW waste handling and are they provided with relevant immunization like Hepatitis B and Tetanus?		X	Frequency of medical examination: Annually	Mostly animal pathogens are handled; those handling zoonotic pathogens are subjected to medical examination, as per requirement. Annual medical check-up will be instituted for persons over the age of 40 years from 2021.
27.	Is a daily register for bio- medical waste maintained including accident reporting record?		X		Record will be maintained as and when they occur
28.	Are annual reports on BWM submitted to SPCB as per required form (see Bio- Medical Waste Rules 2016)?		X		Not currently followed, and will be submitted annually now onwards during the Project.
	Harea of Risk	azarc Yes	lous V No	Vaste (HW) Details	Proposed Plan
			110		_
29.	Is there generation of hazardous waste (as per Hazardous Waste Rules, 2016) in the grantee?	X		list of hazardous waste produced in the facility: Organic solvents and chemicals required for biotechnology research	Hazardous waste generated will be handled and disposed as per HW rules 2016
30.	Is there trained staff in the facility to identify and handle hazardous waste?	X		A committee overseas the identification and handling of hazardous waste	New personnel will also be trained before getting part of the project implementation team.
31.	Does the grantee have authorization from SPCB for hazardous waste?	X			Authorizations will be renewed from time to time.
32.	Is there a secure location for storage of HW with proper signage?	X		Separate location used, and is away from laboratories or office, and not affecting	Will continue to follow the same process throughout the project.

	Are hazardous waste stored for more than 90 days in the grantee's premises?		X	material or personnel movement	
33.	Is the hazardous being send to an authorized disposal facility or user? Is the disposal facility in house? Is the disposal facility	X	X X	Name and address of facility: GJ Multiclave, Hyderabad	The disposal facility is government authorized and NIAB will continue to monitor the process and quality standards offered
	external/outsourced?				by the outsourcing authority.
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?		X		The authorized vendor picks up the material We will maintain the register when required.

		E-	Wast	e and Batteries:	
	Area of Risk	Yes	No	Details	Proposed Plan
35.	Does the grantee generate e- waste, produce or manufacture electrical and electronic equipment?		X	In our activity we do not generate the E-Waste and Batteries	Essential measures will be taken as and when the need arises during the project.
36.	Has the grantee obtained SPCB authorization on e-waste?		X	In our activity we do not generate the E-Waste and Batteries	Necessary Authorizations will be taken if required.
37.	Does the grantee channelize the e-waste to authorized recycling or disposal facility? Not applicable		X	In our activity we do not generate the E-Waste and Batteries	As and when the need arises proper system will be put in place during the project.
38.	Does the manufacturing grantee have Extended Producer Responsibility system and EPR-authorization in place?		X	In our activity we do not generate the E-Waste and Batteries	We do not plan to enter into manufacturing in near future. But if the case, will ensure the EPR system in place.
39.	Does the grantee practice reduction in the usage of hazardous substances in the manufacture of electrical and electronic equipment and its parts?		X	In our activity we do not generate the E-Waste and Batteries	We do not use hazardous substances and are not involved in manufacturing of electrical and electronic equipment or its part.

		Yes	No	Details	Proposed Plan
				nd Safety and risk mitigation	
	2000 and ensure collection of old batteries?				
48.	In case of manufacturing, does the grantee comply to Battery Management Rules		X	In our activity we do not generate the E-Waste and Batteries	manufacturing, sale or collection of batteries
47.	Does the grantee deposit the battery waste to registered recycler/dealer/manufacturer/rec onditioner/collection center?		X	In our activity we do not generate the E-Waste and Batteries	We do not foresee any battery-waste in near future. But if the case arises in future, will do the needful. We do not deal with
46.	Does the grantee generate battery waste?		X	In our activity we do not generate the E-Waste and Batteries	We do not deal with manufacturing, sale or collection of batteries.
45.	Is the grantee involved in manufacture of batteries?		X	In our activity we do not generate the E-Waste and Batteries	We do not deal with manufacturing, sale or collection of batteries.
44.	Are PPEs available to staff?		X	In our activity we do not generate the E-Waste and Batteries	The stock status of PPE will be regularly monitored and if required adequate procurement will be done in time.
43.	Is there accident reporting and records in place?		X	In our activity we do not generate the E-Waste and Batteries	The system is in place, however no incident has happened and hence recorded yet
42.	Does the grantee submit annual reports on e-waste to SPCB?		X	In our activity we do not generate the E-Waste and Batteries	We do not foresee any e- waste in near future. But if the case, will do the needful.
41.	Does the grantee maintain a record of collection, storage, sale and transport of e- waste?		X	In our activity we do not generate the E-Waste and Batteries	We do not deal with the manufacturing, sale or collection of electronic or electrical items and do not foresee any e-waste in near future. But if the case, will do the needful.
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?		X	In our activity we do not generate the E-Waste and Batteries	We do not use hazardous substances and are not involved in manufacturing of electrical and electronic equipment or its part

49.	Safety Transportation	X		All hazardous waste picked up	Will continue the same
τ <i>)</i> .	Management System (for	Δ		by designated waste collector	process
	transport of hazardous material)			approved by SPCB	
50.	Emergency preparedness and	X		Liaison with and through local	Emergency Plan will be
	participation of local authorities			and state authorities	maintained.
	and potentially affected				
	communities				
				Other	
	Area of Risk	Yes	No	Details	Proposed Plan
51.	Does the grantee use any		Х		Setting up a separate
	radioactive materials (isotopes				radiation room with
	tracers, radiation equipment,				equipment, detectors,
	etc)?				storage & disposal
	Does the grantee have		Χ		mechanisms as per AERB
	appropriate radioactive material and waste storage and disposal				is in process.
	system in place?				
	Are radioactive warning signs in		X		-
	place?		1		
52.	Is the lab/room air		X		Will be implemented if
	regularly checked for				required
	microbial contamination?				1
					Periodic checks will be
					done if required
53	Are there any odor control	Х		Exhaust systems	Periodic checks will be
	measures in place?				done preventive measures
					will be taken.
54.	Are fume hoods and	Х		Under AMC or regular	Periodic checks and
	exhausts regularly checked			maintenance	maintenance will be done.
55.	and maintained? Does the grantee use DG set >	X			DG sets emissions will be
55.	15 KVA?	Λ			regularly monitored as per
	Does the grantee have consent	X		-	CPCB norms.
	for $DG > 15 \text{ KVA}$?	11			
	Are emissions from	X		-	
	boilers and DG sets				
	regularly monitored to be				
	within the prescribed				
	norms?				
56.	Does the grantee have proper	X			It will be ensured that
	disposal process for solid and				segregation rules are
	plastic waste in compliance to				followed. This will be
	Solid Waste Management				maintained and
	Rules, 2016 and Plastic Waste				monitored.
57	Management Rules, 2016?	v		Trunce of most mutants I i i	INIAD along to continue to
57.	Is wastewater treated	Х		Types of wastewater: Liquid	-treat the waste separately
	separately by the			waste from laboratory, non	-meat the waste separately

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	grantee? (Liquid waste from laboratory, chemicals, fluids, solvents, medium and cultures, coolants, etc.)			hazardous chemicals, fluids, solvents, medium and cultures, sewerage Treatment of wastewater: Bioling, STP Chemical management in wastewater treatment plants; Not carried out as non-	procedures followed.
				hazardous chemicals are not	t
	A .4 4 4 .	37		released	
	Are there sludge management and cut off drains in place for wastewater?	Х			Defined ETP plant procedures will be continued to be followed for best sludge management practices.
58.	Are necessary provisions for noise cancellation in place?		Х		Preventive measures will be taken for reducing noise levels if generated
59.	Are there any settlements, water bodies, cultivated land, or any other eco-sensitive areas near the grantee's premises?		Х		Nothing closeby
60.	Are there any buffers, fire vehicle routes in the grantee's premises?	X		Fire tender movement road is available around the building.	The available routes will ensure free flow of vehicles in any kind of emergency.
COV	TD Precautions & Guidelines Im	pleme	entati	on	
61	Guidelines of CPCB/SPCB/GoI for Handling, Treatment, and Disposal of COVID Waste Generated is whether being followed?		X		No COVID waste being generated. However, in case of any such waste generated we will follow the guidelines issued by CPCB/SPCB/GoI for COVID waste generation.
62	Whether SOP on preventive measures to contain spread of COVID-19 issued by ICMR/GoI from time to time is being followed?	Х		All procedures are being followed, including isolation/ quarantine, santization, physical distancing, face mask etc.	Guidelines issued by ICMR/GoI will be followed. Preventive measures to contain the spread of COVID-19 will be followed time to time in the future also.

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.