

Environmental and Health Risk Management Plan (EHRMP)

Amrita Vishwa Vidyapeetham

Proposal entitled: Mandibular bone augmentation with an indigenous developed novel fiber reinforced composite scaffold: A pilot clinical trial

i) Brief description of the proposed activity:

The product will be developed under GMP clean room facility under the strict safety guidelines. All work surfaces will be decontaminated before and after performing the work. Non-infectious material will be sent for incineration. Robust containers will be used to keep broken glass, needles and syringes in order to protect workers from injury. All the waste aqueous and organic solvents after fabrication will be collected in appropriate containers and discard through waste management system of Amrita Hospital. Personnel protective clothing will be selected specifically for the work place, depending on concentration and quantities of the hazardous substances handled. The chemical resistance of the protective equipment should be enquired at the respective supplier. No ecological problems are to be expected when the product is handled and used with due care and attention. Contamination of drains, water and soil will be avoided.

ii) List of environments related regulatory clearances required for the activity:

All the waste aqueous and organic solvents after fabrication will be collected in appropriate containers and discard through biomedical waste treatment facility of Amrita Institute of Medical Science that follows BMW rules 2016 amendment. Besides, waste pre-treatment equipment, which adhere to the norms of Kerala State Pollution Control Board is there in the premise. The state pollution control board certificate is attached. The MOU with government authorised waste disposal agency is also attached

		Yes	No	Details	Proposed Plan
Institutional Arrangement					
1.	Is there a designated full-time staff for Environment Health and Safety (EHS) issues?	X		Safety & facility safety Officer in place. Office of the Superintendent in charge Adherence to ISO 18001: 2015	Each morning any deviation of SOPs and harm are discussed
2.	Does the EHS staff handle the following?			Adherence to ISO 18001: 2015	Regular audit are conducting to check adherence.
	Occupational Health and Safety	X			
	Waste Management	X			
	List of consents and regulatory clearances	X			
	Record keeping of accidents and procedures	X			
	EHS trainings for staff	X			
	Environment Management Framework compliance for	X			

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	Innovate in India Project				
3.	Is there a reporting structure in place regarding EHS issues?	X		Incident Reporting format and protocol in place. Any staff, health care personnel or patient can escalate health safety issue which is discussed in Morning meeting and Clinical Ethics Committee	Incident report meeting are conducting monthly basis and assure proper corrective and preventive actions are in place to avoid recurrence.
4.	Are regular EHS trainings provided to staff?	X		Frequency: Annual	To address induction training of new employees
General Occupational Health and Safety					
5.	Are there Standard Operating Procedures for accidents, hazards, and other emergencies (chemical spills, heat hazards, fire hazards, radioactive hazards etc.)?	X		Hazard Identification and Risk Analysis (HIRA) Document in place. Reporting structure in place	SOP in place As per ISO 9001:2015, NABH, PCB norms
6.	Are the following in place?			Code Orange SOP in place; training provided to each employee. Spill kits for minor and major spill conducted (As per NABH 4 th edition norms)	Eye wash facility, first aid kit, extinguishers have been provided in the facility where ever needed. Registers are maintained by concerned dept. staff.
	Chemical spill kits	X			
	Eye wash	X			
	Shower stations	X			
	First Aid Kit	X			
	Fire Extinguishers	X			
7.	Are proper signage and storage system in place?	X		High risk material and chemical items are color coded and MSDS provided for flammable items	External and internal signages are in place and are subjected to monthly audits.
	Display of Material Safety Data Sheet (MSDS) where relevant	X		Stock registers are available in the warehouse. Receipt and issue will be recorded promptly.	MSDS display ensured in all areas where inflammable items are using/storing.
	Display of emergency numbers and procedures (Person to Contact, Doctor, Ambulance, Fire Emergency, Police) displayed in all critical places	X			
	Signage across the facility (labs, storage, hazardous areas, etc.)	X		Organic solvents are stored in separate fume hood.	
Are flammable materials appropriately stored to prevent fire hazards?	X		Adhere to NBC 2005 norms and NABH norms		
8.	Are smoke detectors, fire alarms, automatic safety/shutoff systems, overflow preventers, etc. in place and	X		All in place to adhere to NBC 2005(For fire)	Regular audits are conducted to ensure the smooth functioning.

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	regularly maintained?					
9.	Are there control measures for VOC, air emissions, high operating temperatures, pathogens/vectors etc. in place?	X		VOC, Emission monitoring (AGSS, Formalin etc) in place; BSL 2 & 3 is in place		
10.	Are regular mock drills conducted for emergency preparedness and safety?	X		Frequency 6 monthly As per NABH norms	Code blue, code pink, code orange, code red mock drills has been conducted and staffs are being trained .	
11.	Are staff provided with OHS training?	X		Induction and Periodic training provided to all employees As per NABH norms	100% adherence on OHS to every staffs. Training calendar and attendance sheet available	
Biomedical Waste (BMW)						
12.	Is there generation of biomedical waste (as described in Bio-Medical Waste Management Rules, 2016) in the grantee?	X		Biomedical (anatomical, microbiological, pathological waste-infectious; plastic, needles, cytotoxic) and Non Biomedical waste (stationary, food etc) All waste is treated in facility as per Bio-Medical Waste Management Rules, 2016	Institution has it's own biomedical waste treatment facility.	
13.	Is there trained staff to handle biomedical waste in the grantee?	X		All staff are provided training at induction and periodic basis along with feedback as per NABH norms	Staffs are trained	
14.	Has the grantee obtained authorization from State Pollution Control Board /Pollution Control Committee?	X		Consent to operate present for Air, Water and BMW As per Pollution control board of Kerala norms	Consent taken	
15.	Is the biomedical waste segregated at point of generation in the facility and stored in suitable containers?	X		Yellow	Yes	Containers are available according to the latest BMW rules 2016
				Red	Yes	
				White	Yes	
				Blue	Yes	
16.	Is the bar code system for the	X		Not yet, since CTF does		

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	segregated waste in place?			not operate in Kochi and all waste are treated at facility. Incinerator, chemical dis-infection, shredder, Biogas plant etc present at facility	
17.	Is the biomedical waste being sent to an authorized common BMW facility?		X	In house BMW facility available	Will maintain this facility treating biomedical waste throughout the Project.
18.	Does the grantee have an in-house BMW treatment facility?	X		Authorization:	Institution possess own BMW treatment facility as per BMW rules 2016 amendment and will maintain this throughout the Project.
	Is the treatment facility own (individual)?	X		The facility is authorized by state pollution control board.	
	Is the treatment facility a shared facility in an industrial park?		X	Distance of nearest CBWM from facility: It is a distance of 280 km from hospital campus	
19.	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?	X		Both water Treatment Plant (WTP) & Effluent Treatment Plant (ETP) are there in the premise. We follow color coded bag system for disposal as per Biomedical Waste Management Rules, 2016. Yellow bags are used for collection of body parts, infected cotton and microbiology waste. Red bags are used for contaminated recyclable waste. White bags are meant for sharps. These are pre-treated with 1% hypochlorite solution before being bagged and sent to incinerator. The incinerator ash is considered as hazardous	Will be done as per BMW rules 2016 amendment and NABL norms (ISO 15189)

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				and is then handed over to the authorised recycler KEIL Kerala Environmental Infrastructure Limited (MOU attached). There are 2 incinerators, only one is used at a time while the other is on standby	
20.	Is the liquid waste checked for active cells before sending to treatment plant?	X		Routine testing is not carried out. But periodically these are checked for fungal and bacterial colonization in our NABL accredited lab	Will be done as per ISO 15189
21.	Are necessary waste pre-treatment equipment in place?	X		We have waste pre-treatment equipment is there, which includes: <ul style="list-style-type: none"> • Incinerator: Dual chamber • Autoclave along with chemical treatment facility • ETP and STP • Biogas 	All equipment/machines are and will be possessed by WTP/ETP departments in the same premise. Pollution Control Board norms will be followed. Wastes related with GMP manufacturing process shall be collected in a suitable container and forwarded to WTP as per the SOP.
	Do the equipment adhere to prescribed norms by State Pollution Control Board (SPCB)?	X			
22.	Are non-chlorinated plastic gloves and bags phased out in the grantee?	X			Will be treated as per BMW 2016 amendment
23.	Are grantee's personnel involved in handling BMW provided with regular training?	X		Frequency: Once in 3 months Trainer: Patient safety Officer and Infection Control Officer	Will be trained in infection control practices and occupational safety aspects.
24.	Are medical examination provided to personnel involved in BMW waste handling and are they provided with relevant immunization like Hepatitis B and Tetanus?	X		Immunization details are maintained by Infection control department As per NABH norms	This will be maintained as per NABH norms

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25.	Is a daily register for biomedical waste maintained including accident reporting record?	X		As per BMW 2016 amendment norms and reports submitted.	This register will be maintained for the entire duration of the Project.
26.	Are annual reports on BWM submitted to SPCB as per required form (see Bio-Medical Waste Rules 2016)?	X		Annual reports are being shared in the hospital website as per rule.	Will be done as per PCB norms
Hazardous Waste (HW)					
27.	Is there generation of hazardous waste (as per Hazardous Waste Rules, 2016) in the grantee?	X		Generated hazardous waste like Used oil from DG sets, ETP sludge, Incinerator ash are collected by authorised agency for disposal as per guidelines (MOU attached)	Will adhere to BMW 2016 amendment
28.	Is there trained staff in the facility to identify and handle hazardous waste?	X		All staff are trained They will identify and handle hazardous waste as per SOPs	Further trainings will be scheduled as per NABH norms for fresh recruits as and when needed.
29.	Does the grantee have authorization from SPCB for hazardous waste?	X		PCB/HO/EKM-1/ICO-R15/2018	Timely renewals will be done and proper authorization will be obtained.
30.	Is there a secure location for storage of HW with proper signage?	X		There is demarcated premise for waste segregation	Will use the demarcated premises for waste segregation during the Project.
	Are hazardous waste stored for more than 90 days in the grantee's premises?		X		
31.	Is the hazardous being send to an authorized disposal facility or user?	X		Incinerator ash is collected by the authorized agency (MOU attached)	Future disposal of hazardous waste will be done by the authorized agency as per HW Rules 2016.
	Is the disposal facility in house?	X			
	Is the disposal facility external/outsourced?		X		
32.	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			It will be maintained as per norms of Amrita Institute.
E-Waste and Batteries					
33.	Does the grantee generate e-waste, produce or manufacture electrical and	X		Computer equipment	Waste will be outsourced.

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	electronic equipment?				
34.	Does the grantee channelize the e-waste to authorized recycling or disposal facility?	X		Name and address of disposal facility/ recycler: Smart Bio-solutions	The practiced will be followed throughout.
35.	Is the grantee involved in manufacture of batteries?		X		
36.	Does the grantee generate battery waste?		X	The batteries and electronic waste is collected and disposed by authorized agents	This process will be followed as per existing rules and regulations with the authorized agents.
Others					
37.	Does the grantee use any radioactive materials (isotopes tracers, radiation equipment, etc.)?	X		Adherence to AERB and BMW 1996	Audit will be conducted by Radiation safety dept.
	Does the grantee have appropriate radioactive material and waste storage and disposal system in place?	X		Adherence to AERB and BMW 1996	Audit will be conducted by Radiation safety dept.
	Are radioactive warning signs in place?	X		Signage's as per AERB Guidelines	Regular audits will be done.
38.	Is the lab/room air regularly checked for microbial contamination?	X		By air sampling In GMP, settle plate method for microbial monitoring shall be performed on daily basis. Air sampling, particle counting, and HEPA filter validation also performing as per ISO and EU guidelines	This will be done by microbiology dept. and hospital safety dept.
39.	Are there any odor control measures in place?	X			Will ensure to upgrade and use better measures to mitigate the odor produced.
40.	Are fume hoods and exhausts regularly checked and maintained?	X		Air tests	Regular audits by Biomedical and hospital safety team will be done.
41.	Does the grantee use DG set > 15 KVA?		x	Air test done periodically	This is not applicable to our institute currently.

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	Does the grantee have consent for DG > 15 KVA?				
	Are emissions from boilers and DG sets regularly monitored to be within the prescribed norms?	X			
42.	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?	X		Mostly done in house but some sent to authorised recycling agencies.	BMW 2016 amendment Act will be adhered throughout.
43.	Is wastewater treated separately by the grantee? (Liquid waste from laboratory, chemicals, fluids, solvents, medium and cultures, coolants, etc.)	X		As per BMW 2016 amendment	Periodic checkup will be done.
	Are there sludge management and cut off drains in place for wastewater?	X			
44.	Are necessary provisions for noise cancellation in place?	X			The noise levels will be monitored and maintained periodically.
45.	Are there any settlements, water bodies, cultivated land, or any other eco-sensitive areas near the grantee's premises?	X		Backwaters are there, which is 2 km away from premise	Hospital will be taking every measure to ensure that it is not getting polluted by any means by hospital wastes.
46.	Are there any buffers, fire vehicle routes in the grantee's premises?	X			Will keep updating these as per requirements in the project.

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.