

Environment Health Risk Management Plan (EHRMP)

Amrita institute of medical sciences

Proposal entitled: To establish Clinical Trial Networks for hospital-based trial in Ophthalmology

1. Institutional Arrangements

<p>(i) Brief description of the proposed activity- A clinical trial network comprising 6 centers will be made and a clinical trial registry maintained on the eye diseases which may require biologics and Indian biosimilars</p> <p>(ii) List of environments related regulatory clearances required for the activity. ISO 18001:2015, BMW rules, NABH, pollution control rules, Kerala, PCB norms</p>					
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?	X		Patient Safety & facility safety Officer in place. Office of the Hospital Superintendent in charge Adherence to ISO 18001: 2015	Each morning any deviation of SOPs and harm along with near miss 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 Innovate in India Project	X			
3.	Is there a reporting structure in place regarding EHS issues?	X		Incident Reporting format and protocol in place. Any HCP 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

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5.	Institutional Bio-Safety Committee (IBSC)	X		As per the BMW Rules 2016	Hospital safety committee meetings happening quarterly basis
6.	Ethics Committee (EC)	X		IEC/IRB in place As per NABH norms	Institutional ethics committee exists. Meeting happening on monthly basis.
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.)?	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
8.	Are the following in place?			Code Orange SOP in place; training provided to each employee. Spill kit 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 department staff.
	Chemical spill kits	X			
	Eye wash	X			
	Shower stations	X			
	First Aid Kit	X			
	Fire Extinguishers	X			
	Register of accidents and injuries	X			

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9.	Are proper signage and storage system in place?	X		High risk material and chemical items are color coded and MSDS provided Flammable items adheres to NBC 2005 norms and NABH norms	External and internal signages are in place and are subjected to monthly audits. MSDS display ensured in all areas where inflammable items are using/storing.
	Display of Material Safety Data Sheet (MSDS) where relevant	X			
	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			
	Are flammable materials appropriately stored to prevent fire hazards?	X			
10.	Are smoke detectors, fire alarms, automatic safety/shut off systems, overflow preventors, etc. in place and regularly maintained?	X		All in place to adhere to NBC 2005 (For fire)	Regular audits are conducted to ensure the smooth functioning.
11.	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	Institute will ensure that these things are in place in coming days as well.
12.	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 . And this thing will continue on ongoing basis to keep everyone updated.
13.	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)					
	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?	X		Biomedical (anatomical, microbiological, pathological waste-infectious; plastic, needles, cytotoxic) and Non Biomedical	Institution has its own biomedical waste treatment facility.

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				waste (stationary, food etc) All waste is treated in facility Bio-Medical Waste Management Rules, 2016		
15.	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 an on periodic basis it will be ensured that they are getting trained on any updated knowledge as applicable.	
16.	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	Approval has been taken and it will be ensured that it is getting renewed before expiry.	
17.	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	
18.	Is the bar code system for the segregated waste in place?	X		Not yet, since CTF does not operate in Kochi and all waste are treated at facility. Incinerator, chemical dis-infection, shredder, Biogas plant etc present at facility	If the norms change, then only we will go into bar code system for segregated waste	

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19.	Is the biomedical waste being sent to an authorized common BMW facility?		X	Name and address of CBMWFNA Distance from facility: Frequency and Mode of transport: Who transports?	Wastes generated are being treated and handled inside facility [remises only].
20.	Does the grantee have an in-house BMW treatment facility?	X		Reason:	Institution possess own BMW treatment facility As per BMW act 2016 amendment
	Is the treatment facility own (individual)?	X		Authorization: State PCB	
	Is the treatment facility a shared facility in an industrial park?		X	Distance of nearest CBWM from facility: 280kms Types of treatment:	
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?	X		Types of treatment: Both ETP and STP present at facility. Water post treatment is monitored	As per BMW act 2016 amendment and NABL norms (ISO 15189)
22.	Is the liquid waste checked for active cells before sending to treatment plant?	X		Water quality monitored. Tested by NABL lab	Routinely done as per (ISO 15189) standards.)
23.	Are necessary waste pre-treatment equipment in place?	X		List of equipment (autoclaves, shredders, incinerators, etc.):	All equipments/machines are possessed by WTP/ETP departments in the same premise.as per PCB norms
	Do the equipment adhere to prescribed norms by State Pollution Control Board (SPCB)?	X		Details of waste pre- treatment: Incinerator: Dual chamber Autoclave along with chemical treatment facility +	

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				ETP and STP Biogas +	
24.	Are non-chlorinated plastic gloves and bags phased out in the grantee?	X			As per BMW 2016 amendment
25.	Are grantee's personnel involved in handling BMW provided with regular training?	X		Frequency: 3 monthly Trainer: Patient safety Officer and Infection Control Nurse	Trained in infection control practices and occupational safety aspects.

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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 Vaccination as per schedule	Immunization details are maintained by Infection control department As per NABH norms
27.	Is a daily register for biomedical waste maintained including accident reporting record?	X		As per BMW 2016 amendment norms and reports submitted	Regularly monitored and updated
28.	Are annual reports on BWM submitted to SPCB as per required form (see Bio-Medical Waste Rules 2016)?	X		As per PCB norms	Annual reports are being shared in the hospital web site as per rule.
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?	X		Anatomical, Microbiological waste Infectious and non-infectious plastic Needles Cytotoxic & Radioactive Air monitoring Water: STP & ETP If No, provide a list of all waste produced in the facility.	This will be handled as per BMW 2016 amendment
30.	Is there trained staff in the facility to identify and handle hazardous waste?	X		All staff are trained	Training has been provided by Hospital safety and infection control department as per NABH norms
31.	Does the grantee have authorization from SPCB for hazardous waste?	X		Yes, consent from the state pollution control board to generate, store and dispose hazardous waste	It will be ensure to have approval from SPCB as per norms.

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32.	Is there a secure location for storage of HW with proper signage?	X		Colored coded bags Platforms: Incinerator, distances from critical installations: 100m/movement areas: Covered trolleys, spill collectors: all locations and floors, gas escape facility: All OTs and Pathology section, etc.	There is demarcated premise for waste segregation
	Are hazardous waste stored for more than 90 days in the grantee's premises?		X		
33.	Is the hazardous being send to an authorized disposal facility or user?	X		Name and address of facility: User facility (Amrita Institute)	Hazardous waste will be disposed as per hospital SOP.
	Is the disposal facility in house?	X			
	Is the disposal facility external/outsourced?		X		
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			It will be maintained as per norms of Amrita Institute.

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?	X		Computer equipment Outsource waste Earth E- Waste Management Pvt. Ltd., Block No. 63, Sagun Ind. Estate, ... Hanumanthap pa Layout, Mysore Road, Bangal ore -. 560039.	This will be handled as per proposed applicable plan.

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36.	Has the grantee obtained SPCB authorization on e-waste?	NA			This is not applicable to us.
37.	Does the grantee channelize the e-waste to authorized recycling or disposal facility?	X		Earth E-Waste Management Pvt. Ltd., Block No. 63, Sagun Ind. Estate, ... Hanumanthappa Layout, Mysore Road, Bangalore -. 560039. 300. 3.	Proper recycling of e-waste will be ensured during the project conduct.
38	Does the manufacturing grantee have Extended Producer Responsibility system and EPR-authorization in place?			<i>No manufacturing</i>	NA
39	Does the grantee practice reduction in the usage of hazardous substances in the manufacture of electrical and electronic equipment and its parts?	NA		No manufacturing	NA
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?	NA		No manufacturing	NA
41	Does the grantee maintain a record of collection, storage, sale and transport of e-waste?	Yes			As per E-waste policy of AIMS
42	Does the grantee submit annual reports on e-waste to SPCB?			This will be discussed with the concerned department and details if required will be shared later	E waste policy of AIMS
43.	Is there accident reporting and records in place?	Yes		Accident reporting and record system is in place.	Proper accident reporting system will be ensured during the entire project conduct.

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44.	Are PPEs available to staff?	Yes			This will be made available to staffs as and when required.
45.	Is the grantee involved in manufacture of batteries?	No			This is not applicable to us.
46	Does the grantee generate battery waste?	NA			This is not applicable to us.
47	Does the grantee deposit the battery waste to registered recycler/dealer/manufacturer/reconditioner/collection center?	NA			This is not applicable to us.
48	In case of manufacturing, does the grantee comply to Battery Management Rules 2000 and ensure collection of old batteries?	NA		There is no manufacturing of batteries at AIMS	In case of manufacturing, shall comply
Community Health and Safety and risk mitigation					
		Yes	No	Details	Proposed Plan
49.	Safety Transportation Management System (for transport Of hazardous material)	X		Covered trolleys Lead lined containers & Delay tanks: For radioactive	Dedicated transport system will be used
50.	Emergency preparedness and participation of local authorities and potentially affected communities	X		Disaster Codes: Code Orange	This will be followed as per plan

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Other					
	Area of Risk	Yes	No	Details	Proposed Plan
51.	Does the grantee use any radioactive materials (isotopes tracers, radiation equipment, etc)?	X		Adherence to AERB and BMW 1996	Audit conducted by Radiation safety dept
	Does the grantee have appropriate radioactive material and waste storage and disposal system in place?	X		Describe: same as above	Yes Audit conducted by Radiation safety department
	Are radioactive warning signs in place?	X		Signage's as per AERB Guidelines	Audit conducted by Radiation safety department
52	Is the lab/room air regularly checked for microbial contamination?	X		By Air sampling	Done by hospital safety department.
53	Are there any odor control measures in place?	X			
54	Are fume hoods and exhausts regularly checked and maintained?	X		Air tests	Regular audits by Biomedical and hospital safety team
55	Does the grantee use DG set > 15 KVA?		X	Air test done periodically	This is not applicable to our institute currently.
	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			
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?	X		Describe: As per BMW 1996 norms 2016 amendment	BMW 2016 amendment
57	Is wastewater treated separately by the grantee? (Liquid waste from laboratory, chemicals, fluids, solvents, medium and cultures, coolants, etc.)	X		Types of wastewater: Treatment of wastewater: STP & ETP Chemical management in	Periodic check up done by hospital concerned department.

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			wastewater treatment plants: ETP (BMW norms) BMW 2016 amendment	
	Are there sludge management and cut off drains in place for wastewater?	X	Yes by water treatment plant	
58	Are necessary provisions for noise cancellation in place?	X	The noise levels will be monitored and maintained periodically.	The noise levels will be monitored and maintained periodically.
59	Are there any settlements, water bodies, cultivated land, or any other eco-sensitive areas near the grantee's premises?	X	Describe: Backwaters Distance from premises: 10 m	Hospital is taking every measures to ensure that it is not getting polluted by any means by hospital wastes.
60.	Are there any buffers, fire vehicle routes in the grantee's premises?	X		These are as per required policy.

Notwithstanding the above, other risks that will be relevant to the project activities, identified in due course, shall be addressed as per standard mitigation measures. Monitoring parameters and manner of record keeping shall be in accordance to the recommendations of the project monitoring committee or subject expert engaged by BIRAC