

Environmental Health Risk Management Plan (EHRMP)

Gokula Education Foundation, (MSRMCH)

Proposal entitled: Clinical trial network for hospital-based trials in Diabetology

1. Institutional Arrangements

- (i) Brief description of the proposed activity-
 The hospital has a very active Biomedical waste management committee which monitor all the activities so that biomedical waste collection, segregation happens in compliance with the BMW management rules 2016.
 Hospital has the required infrastructure, processes and monitoring mechanism in place for management of Bio medical waste which is generated. All hospital staff are provided with PPE and training on use of the same.
 Hospital has experienced trainer who provide training to the nursing staff, BMW management staff, and housekeeping staff on BMW collection, segregation, color coding, Bar code scanning etc as per the BMW management rule 2016.
 Monitoring of the BMW is strictly implemented in critical area like ICU, OT, ANE, Labor room. Monthly and annual reporting system of BMW generated is in place which is submitted to Karnataka SPCB on regular basis.
- (ii) List of environments related regulatory clearances required for the activity-
 Air waste Management Act
 Solid waste Management Act
 Biomedical Medical Waste Management Act
 Karnataka State Pollution Control Board

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?		No		Based on the requirement a Consultant will be hired on need basis. The institute will comply with the norms and requirements of the Pollution Control Board.
2. Does the EHS staff handle the following?		No	Currently EHS staff is not available. Occupational Health Safety handling is conducted by the	Necessary and mandatory approvals will be taken as and when required. Once approval/registration is
Occupational Health and Safety		No		
Waste Management		No		
List of consents and regulatory clearances		No		
Record keeping of accidents and procedures		No		

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	EHS trainings for staff		No	trained clinicians, and lab staff.	done, all staff dealing with above shall be trained in consultation with SPCB and other authorities.
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	Environment Management Framework compliance for Innovate in India Project		No		
3.	Is there a reporting structure in place regarding EHS issues?	No		Describe: Currently EHS staff is not available. Occupational Health Safety handling is conducted by the trained clinicians, and lab staff.	All aspects of Environmental Health Safety (EHS) is reported to the Registrar- Administration who in turn escalates the same to the Dean and higher management as appropriate. The institution is NABL as well as NABH accredited and conforms to the safety and quality assurance requirements as per the stipulated guidelines. The certifications from the State Pollution Control Board under the various proviso is obtained. Independent committees pertaining to issues of infection control, laboratory safety, occupational health, and wellbeing are in place. Annual compliance reports will be generated from the registers and records maintained at the institutional level to ensure adherence to the requirements.
4.	Are regular EHS trainings provided to staff?	No		Frequency: NA	Staff EHS trainings are planned which will be as per the guidelines provided by SPCB.
5.	Institutional Bio-Safety Committee (IBSC)	No			Presently, research activities involving recombinant DNA technology are not

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					undertaken within the institution. Our institution has an MOU with IISc for such research activities wherein the IBSC and other compliance requirements are well in place. Any activity involving recombinant DNA use will be undertaken in compliance with the existing norms and requirements of the DBT guidelines.
6.	Ethics Committee (EC)	Yes		The Institutional Ethics Committee is constituted as per DCGI guidelines and is registered with DCGI and is NABH accredited.	Project will be commenced only after getting approval from Ethics Committee (EC).
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.)?	Yes		<ul style="list-style-type: none"> - Emergency preparedness and disaster management manual - Safety for potential hazards - Hospital Safety Manual - Risk Management Manual - Infection control Manual - Biomedical waste management Manual 	Designated separate departments will continue to monitor and follow the SOPs in place. Display of Procedures at prominent places in the site will be ensured.
8.	Are the following in place?				Will be maintained and operated as per the
	Chemical spill kits	Yes			

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	Eye wash	Yes			Institute's guidelines for Environment Health and Safety (EHS).
	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 boards are in place in the required areas.	These would be regularly updated/replaced.
	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 fire hazards?	Yes			
10.	Are smoke detectors, fire alarms, automatic safety/shut off systems, overflow preventors, etc. in place and regularly maintained?	Yes		List: All required infrastructure is available.	These would be regularly maintained.
11.	Are there control measures for VOC, air emissions, high operating temperatures, pathogens/vectors etc. in place?	Yes		List: All required infrastructure is available.	This would be reviewed periodically.
12.	Are regular mock drills conducted for emergency preparedness and safety?	Yes		Frequency (type wise): Monthly once	This will be followed as per the schedule prepared by the Dr. Aruna. C. Ramesh & Ms. Lissy John
13.	Are staff provided with OHS training?	Yes		Describe: Video display method and hands on class	Training includes first aid, addressing medical emergencies, occupational positioning risk, how to avoid wrong postures during working hours, safety data sheet (hazardous medical content prevention and precautions). This shall be updated and reviewed periodically.

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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?	Yes		list of biomedical waste produced in the facility: -Infected waste; -Contaminated waste(recyclable); - Sharp waste including metals, glassware & metallic implants	Outsourced Organization Anu autoclave & Inc.in, services will be responsible to treat the BMW adhering to Bio-Medical Waste Management Rules, 2016.								
15.	Is there trained staff to handle biomedical waste in the grantee?	Yes		Selected waste collector are trained on PPE, segregation and hands on training is given on scanning	It will be a continual ongoing process.								
16.	Has the grantee obtained authorization from State Pollution Control Board /Pollution Control Committee?	Yes		We have Karnataka State Pollution Control Board license which valid for 5 years. PCB/SEO(WMC)/B MW/Reg No:93884/2015-16/H1507 dated 29 Mar 2016 valid up to 5 years	Renewal will be done as per timelines.								
17.	Is the biomedical waste segregated at point of generation in the facility and stored in suitable containers?	Yes		<table border="1"> <tr> <td>Yellow</td> <td>Yes</td> </tr> <tr> <td>Red</td> <td>Yes</td> </tr> <tr> <td>White</td> <td>Yes</td> </tr> <tr> <td>Blue</td> <td>Yes</td> </tr> </table>	Yellow	Yes	Red	Yes	White	Yes	Blue	Yes	This will be done as per Bio-Medical Waste Management (Amendment) Rules, 2018
Yellow	Yes												
Red	Yes												
White	Yes												
Blue	Yes												
18.	Is the bar code system for the segregated waste in place?	Yes		Bar coding has been implemented as per the BMW management act amendment 2018 and will be regularly updated as per policy guidelines	Bar coding will be regularly updated as per policy guidelines.								

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19.	Is the biomedical waste being sent to an authorized common BMW facility?	Yes		<p>Name and address of CBMWF: Anu autoclave & Inc in, services Sy No. 145/2 Gullahalli village Sulbele hobli, hoskote (talug) Bangalore -562122</p> <p>Distance from facility: 43 Km.</p> <p>Frequency and Mode of transport: Closed transportation and Everyday</p> <p>Who transports: Anu autoclave & Inc in, services</p>	The vendor's contract shall be renewed on time to ensure this practice is being followed.
20.	Does the grantee have an in-house BMW treatment facility?		No	<p>Reason: Outsourced</p> <p>Authorization: Anu Autoclave</p> <p>Distance of nearest CBWM from facility: 7KM</p> <p>Types of treatment: Incineration final disposal method</p>	Will be taken care by Anu Autoclave, Anu autoclave & Inc in, services Sy No. 145/2 Gullahalli village Sulbele hobli, hoskote (talug) Bangalore -562122
	Is the treatment facility own (individual)?		No		

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	Is the treatment facility a shared facility in an industrial park?	Yes			
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: As per BWM 2016 regulation	Compliance calendar shall be maintained.
22.	Is the liquid waste checked for active cells before sending to treatment plant?	Yes		It has been outsourced to an external agency by name Green Enviro Tech Services, which is an NABL Accredited environmental laboratory and the hard copy records of all testing are maintained appropriately.	Routine checks will be done.
23.	Are necessary waste pre-treatment equipment in place?	Yes		List of equipment (autoclaves, shredders, incinerators, etc.): 2 Auto clones Details of waste pre-treatment: Blood bags- Infected liquid waste treatment	Waste generated during this project will be treated as per good lab practices.
	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		Only bags	
25.	Are grantee's personnel involved in handling BMW provided with regular training?	Yes		Frequency: Once in 6 months Trainer: Jansi Mary S	Training calendar will be maintained.

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: Yearly once	Will ensure that it is routinely done.
27.	Is a daily register for biomedical waste maintained including accident reporting record?	Yes		Registered is maintained by Nursing Superintendent/Infection Control Nurse.	This practice would be followed and checked periodically.
28.	Are annual reports on BWM submitted to SPCB as per required form (see Bio-Medical Waste Rules 2016)?	Yes		As per the requirements of the SPCB.	This practice would be followed and checked periodically.
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?	Yes		list of hazardous waste produced in the facility: Used oil & oil filters. There is no usage of blood syringes and sputum.	The collection, treatment and disposal of these hazardous waste generated will comply with the Hazardous Waste Rules 2016.
30.	Is there trained staff in the facility to identify and handle hazardous waste?	Yes		6 month once	Trainings will be conducted o regular basis, new staff will be trained.
31.	Does the grantee have authorization from SPCB for hazardous waste?	Yes		Karnataka SPCB has given authorization for the same SPCB no. PCB/SEO(WMC)/BMW/R eg No:93884/2015-16/H1507 dated 29 Mar 2016 valid up to 5 years	Certificate will be renewed before expiry.
32.	Is there a secure location for storage of HW with proper signage?	Yes		Items are stored with proper signage	The hazardous waste will restored as per SPCB guidelines
	Are hazardous waste stored for more than 90 days in the grantee's premises?		No		
33.	Is the hazardous being send to an authorized disposal facility or user?	Yes		Name and address of facility: Arun Industries, B-64, 3 rd stage, Peenya Industrial area Bangalore-560058	The contract renewal will be done as and when required.
	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?	Yes		Register maintained only for production	In future register will be maintained for treatment also.
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		Only generates	Authorized person from agencies approved by
36.	Has the grantee obtained SPCB authorization on e-waste?	Yes		After disposing e waste through agencies which is approved by Karnataka SPCB, we submit the details to SPCB.	Karnataka SPCB will carry the e waste. The person will give the Form 16 which mentions the details of the e waste. After disposing we submit the details of e waste to Karnataka SPCB.
37.	Does the grantee channelize the e-waste to authorized recycling or disposal facility?	Yes		Name and address of disposal facility/ recycler: HMG Eco care Recycling pvt.ltd. C-22, 3 rd cross, KSSIDC, Industrial estate, Kumbalagodu, Mysore road Bengaluru 560060 Inhouse or outsourced Facility: outsourced	

38.	Does the manufacturing grantee have Extended Producer Responsibility system and EPR-authorization in place?	NA			This is not applicable to us.
39.	Does the grantee practice reduction in the usage of hazardous substances in the manufacture of electrical and electronic equipment and its parts?	NA			This is not applicable to us.
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			This is not applicable to us.
41.	Does the grantee maintain a record of collection, storage, sale and transport of e-waste?	Yes		Record of collection, storage of e waste is available which is maintained in hard copy which is available for review at hospital.	The review of e-waste generated will be done periodically.
42.	Does the grantee submit annual reports on e-waste to SPCB?	Yes		We record the details on monthly basis and annual report of e waste collected is submitted to SPCB	The record will be maintained
43.	Is there accident reporting and records in place?	Yes		Registers are maintained to record any such accidents	Activities under the project will also be recorded
44.	Are PPEs available to staff?	Yes		Available in project site	Ensure Regular provision under the project.
45.	Is the grantee involved in manufacture of batteries?		No		

46.	Does the grantee generate battery waste?	Yes		There are SOPs in place which will be followed and the waste generated is reported to SPCB on regular basis	Battery waste guidelines will be followed.
47	Does the grantee deposit the battery waste to registered recycler/dealer/ manufacturer/ reconditioner/ collection center?		No	Name and address of battery waste receiving entity: NA	
48	In case of manufacturing, does the grantee comply to Battery Management Rules 2000 and ensure collection of old batteries?	NA			This is not applicable to us.
Community Health and Safety and risk mitigation					
		Yes	No	Details	Proposed Plan
49.	Safety Transportation Management System (for transport Of hazardous material)	Yes		Policies, committees and monitoring mechanisms are in place. Healthcare waste management cell which is involved in research training and advocacy activities.	
50.	Emergency preparedness and participation of local authorities and potentially affected communities	Yes		Emergency preparedness Committee in place.	Regular training will be given to the members of the Committee.
Other					
	Area of Risk	Yes	No	Details	Proposed Plan
51.	Does the grantee use any radioactive materials (isotopes tracers, radiation		No	This is to confirm there is no use of any	

	equipment etc.)?			kind of radio-active substances in the project or at the sites	
	Does the grantee have appropriate radioactive material and waste storage and disposal system in place?		No		
	Are radioactive warning signs in place?	Yes		Symbols are placed	
52.	Is the lab/room air regularly checked for microbial contamination?	Yes		This is being carried on by maintenance department.	Surveillance will continue on regular basis.
53.	Are there any odor control measures in place?	Yes		Routine monitoring done by maintenance dept.	Periodic cleaning will be done,
54.	Are fume hoods and exhausts regularly checked and maintained?	Yes		Regularly maintained by maintenance department.	Preventive maintenance plan will be put in place.
55.	Does the grantee use DG set > 15 KVA?	Yes		500KVA x 2 are available.	Monthly once boiler emission / Stuck test will be done
	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		Describe: Maintained according to Solid Waste Management Rules, 2016 and Plastic Waste Management Rules, 2016	This will be maintained and monitored by Deputy Hospital Administrator
57.	Is wastewater treated separately by the grantee? (Liquid waste from laboratory, chemicals, fluids, solvents, medium and cultures, coolants, etc.)	Yes		Types of wastewater: Effluents (laundry, OT liquid waste, and Lab liquid waste) and Sewage Treatment of wastewater: ETP and STP and is recycled Chemical management in wastewater treatment plants: Sodium Hypochlorite is used	Treatment methods will be strictly followed
	Are there sludge management and cut off drains in place for wastewater?	Yes		Sewage treatment plant operator takes care of this	

58.	Are necessary provisions for noise cancellation in place?	Yes		Describe: Applicable only for ENT and sleep lab and this is done by constructing sound proof panels.	Will keep reviewing the noise generated and cap them according to the existing cancellation provisions.
59.	Are there any settlements, water bodies, cultivated land, or any other eco-sensitive areas near the grantee's premises?		No	There is no settlements, water bodies, cultivated land, or any other eco-sensitive areas near the grantee's premises Distance from premises: NA	
60.	Are there any buffers, fire vehicle routes in the grantee's premises?	Yes		Our center is well connected with concrete road and adequate space is available within the premises for fire vehicles. Karnataka Fire and emergency services department inspect the center once in a year and give a NOC.	The requisite space for fire vehicles will be maintained.

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