

Annexure 2

Environmental Health Risk Management Plan (EHRMP)

1. Institutional Arrangements

(i) Brief description of the proposed activity:

MCC will conducted the Project entitled “To establish a ready network of clinical trial units across the National Cancer Grid to promote multi-centric collaborative research in the field of drug and device development” is to build and strengthen a network of clinical trial units with the coordination of NCG to promote multi-centric high quality trials for affordable therapy in oncology.

It will include following activities:-

1. To conduct a survey to assess the gaps in terms of human resources, equipment, pharmacy, existing processes (patient database, registries, IT systems, record keeping, EC approval timelines), storage and archival, SOPs, and training.
2. To conduct the training on SOPs and GCP compliance on all clinical trial related activities to all the medical and non-medical staff who are directly involving the research
3. Procurement of common equipment and software for documentation and research
4. To collect and Report of collated REGISTRY data for all the diseases of all applicants of the network - submitted to NCG and BIRAC

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

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?	Yes		Malabar Cancer Centre monitors the EHS issues through a multi-disciplinary committee named “Facility Management & Safety committee” (Ref:)	FMS committee meets regularly as per SOP and discusses the matters related to safety of patients, staff and the visitors. Also monitors the environment related issues. Recommends CAPA to the Admin committee.
2.	Does the EHS staff handle the following?			Any other: Any other: MCC safety manual for Reference MCC/NABH/D M/HSM/35	Regular audit will be conducted to check adherence.
	Occupational Health and Safety	Yes			
	Waste Management	Yes			
	List of consents and regulatory clearances	Yes			
	Record keeping of accidents and procedures	Yes			
	EHS trainings for staff	Yes			



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	Environment Management Framework compliance for Innovate in India Project	Yes		There is a separate monitoring committee for Environment management in MCC	
3.	Is there a reporting structure in place regarding EHS issues?	Yes		MCC follows a structured Induction training and continuous training for the staff. This training includes employee safety, patient safety and environment safety. The employees are trained to report incidences/adverse events.	The adverse /untoward incidents occurring in the hospital will be reported through the Incident Reporting System that are reviewed by the Patient safety committee and Quality Assurance committee.
4.	Are regular EHS trainings provided to staff?	Yes		Frequency: Twice in an year as per the Annual calendar prepared by HRM	EHS trainings included in the regular Annual training calendar.
5.	Institutional Bio-Safety Committee (IBSC)	Yes		MCC has registered IBSC BT/BS/17/697/2 017-PID/509 dated 3.2.2017	The research unit will comply with IBSC of MCC
6.	Ethics Committee (EC)	Yes		MCC has registered IEC, DCGI Registration under Rule 122DD of the Drugs & Cosmetic Rules 1945. ECR/780/Inst/K L/2015/RR-19	The Ethics Committee will be scheduling meetings regularly depending on the requirement. During the meeting, the members will review the new project proposals and also review the progress of the ongoing projects. They will review the ethical, scientific and the informed consent related issues pertaining to research project.
General Occupational Health and Safety					



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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		SOP are defined and documented. Ref: 1. NABH / MCC / FMS / 07 2. NABH / MCC / FMS / 06 3. MCC/NABH/DM/HMHM/36 4. MCC/NABH/DOC/RSP/04	We will continue to enforce the MCC safety manual throught the Project.
8. Are the following in place?				
Chemical spill kits	Yes		Blood and mercury spill kits are placed wherever applicable.	Periodic audit of spillage kits for contents and awareness of spill management will be done by ICN.
Eye wash	Yes			
Shower stations	Yes			
First Aid Kit	Yes			
Fire Extinguishers	Yes			
Register of accidents and injuries	Yes		Eye wash stations are placed in all applicable areas. First aid kit available in all areas Documentation, analysis and implementation of CA PA related to safety incidences are done. Sentinel event analysis is monitored as a monthly key performance indicator. Periodic replacement of	Standard incidence reporting format and process will be practiced across the HCO Monthly near misses, sentinel events analysis reports will be prepared for appropriate actions. Registers will be maintained for extinguishers. Daily checklist for fire extinguishers for its



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			fire extinguishers based on expiry dates done.	operational standards.
9.	Are proper signage and storage system in place?	Yes	Wherever applicable, the contents of the storage box displayed.	Hospital applicable policy will be followed.
	Display of Material Safety Data Sheet (MSDS) where relevant	Yes	List of hazardous chemicals available across the HCO defined and documented.	
	Display of emergency numbers and procedures (Person to Contact, Doctor, Ambulance, Fire Emergency, Police) displayed in all critical places	Yes	MSDS for all chemicals made for reference in all applicable areas.	
	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	Smoke detectors and fire alarms in place in all newly constructed building. The process for installing all the mentioned fire safety devices in the old building approved and work order issued for the same.	Implementation of installation of fire safety devices across the Health Care Organisation (HCO)
11.	Are there control measures for VOC, air emissions, high operating temperatures, pathogens/vectors etc. in place?	Yes	We are having control measures for VOC, air emission are present in	This would be reviewed periodically.
12.	Are regular mock drills conducted for emergency preparedness and safety?	Yes	Frequency: Disaster preparedness- twice annually Fire mock drill- twice annually Hazmat Mock drill- Twice	Periodic review of the mock drill done for Corrective And Preventive Action (CAPA) implementation.



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			annually	
13.	Are staff provided with OHS training?	Yes	OHS training provided as an induction training Continuous training on OHS topics provided as per Annual training calendar prepared by HRM.	Training will be provided to all staff recruited in the project which would be included in the annual plan.

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		If Yes, provide a list of biomedical waste produced in the facility- 1. Human Anatomical Waste: 2. Soiled Waste 3. Expired or Discarded Medicines 4. Chemical Waste 5. Chemical Liquid Waste 6. Discarded linen, mattresses, beddings contaminated with blood or	Bio medical waste management (BMW) at MCC will be monitored by Hospital Infection Control committee. Collection and segregation of BMW at the point of generation itself as per the BMW guidelines 2016. Uniform color-coded bins placed across the HCO for the purpose. Monthly Audit of BMW management practices will be done by Infection Control Nurse (ICN) and the report discussed in monthly Hospital Infection control meetings for CAPA. BMW management is implemented thorough an agreement with outside agency (IMAGE- an initiative of IMA) . Periodic renewal of agreement done.

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15.	Is there trained staff to handle biomedical waste in the grantee?	Yes	<p>All BMW handling staff are trained on OHS.</p> <p>All the staff are trained in segregation and disposal of BMW at the point of generation itself.</p>	<p>Periodic audit of adherence to PPE and staff awareness conducted among BMW handlers.</p> <p>BMW handlers are provided with Hep B and TT vaccination.</p>
16.	Has the grantee obtained authorization from State Pollution Control Board /Pollution Control Committee?	Yes	PCB Kerala has given authorization. PCB/HO/EE2/KNR/IC/06/2017	Monitoring team will submit six monthly data and renewal will be done annually.
17.	Is the biomedical waste segregated at point of generation in the facility and stored in suitable containers?	Yes	<p>Yellow Human anatomical waste, soiled waste, microbiology, biotechnology and other clinical lab waste that can be incinerated</p> <p>Red Contaminated wastes that cannot be incinerated, but needs autoclaving and deep burial.</p> <p>White Sharp needles, sharp</p>	SOP for BMW management will be strictly adhered.

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				metals.	
			Blue	Bottles, vials, expired or discarded medicines,	
18.	Is the bar code system for the segregated waste in place?	Yes	IMAGE	provides the bar code for RED & YELLOW bags	SOP for BMW management will be strictly adhered.

19.	Is the biomedical waste being sent to an authorized common BMW facility?	Yes		Name and address of CBMWF: IMAGE Distance from facility: 202Km Frequency and Mode of transport: Daily by Road Who transports? IMAGE	Continue the standard practice of BMW management as per SOP.
20.	Does the grantee have an in-house BMW treatment facility?	Yes		Autoclave for treating used culture medias and blood bags from blood bank.	Continue the standard practice of BMW management as per SOP.
	Is the treatment facility own (individual)?	Yes			
	Is the treatment facility a shared facility in an	No			
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		Autoclaving of disposed blood bags and culture medias done before sending to CBMWTF.	Continue the standard practice of BMW management as per SOP.
22.	Is the liquid waste checked for active cells before sending to treatment plant?	No		Will monitor this during the Project and if needed will propose a plan of treating the same as per BWM Regulations.	Will monitor this during the Project and if needed will propose a plan of treating the same as per BWM Regulations.

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2 3.	Are necessary waste pre-treatment equipment in place?	Yes		List of equipment (autoclaves, shredders, incinerators, etc.):	Regular monitoring shall be done adhering to the norms of SPCB.
	Do the equipment adhere to prescribed norms by State Pollution Control Board (SPCB)?	Yes		Details of waste pre-treatment:	
2 4.	Are non-chlorinated plastic gloves and bags phased out in the grantee?	Yes		All used gloves are disposed of in yellow biohazard bags	This practice will be followed.
2 5.	Are grantee's personnel involved in handling BMW provided with regular training?	Yes		Frequency: at least Twice in an year and as per the CA recommended by the HIC committee Trainer: Infection control Team.	Training will be provided to the staff handling biomedical waste as per the existing frequency mentioned. Training details will be documented.
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: Once per year with Hepatitis B and Tetanus immunization	This practice will be checked periodically and compliance will be ensured.
27.	Is a daily register for biomedical waste maintained including accident reporting record?	Yes		Daily register with mention about the weights collected from different areas.	This practice will be checked periodically and compliance will be ensured.
28.	Are annual reports on BWM submitted to SPCB as per required form (see Bio-Medical Waste Rules 2016)?	Yes		Submitted last year report	This practice will be checked periodically and compliance will be ensured.

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	Yes		Diaminobenzidine, propylene and xylene, alcohol and mercury, formalin	Disposal shall be as per BMWM rules throughout the Project.
30.	Is there trained staff in the facility to identify and handle hazardous waste?	Yes		Lab safety officer is appointed who will	This practice will be checked periodically and compliance will



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				periodically update the hazardous chemicals being used in the HCO and submit the report on hazardous chemical waste generated.	be ensured.
31.	Does the grantee have authorization from SPCB for hazardous waste?	Yes		SPCB, Kerala	Timely proper and relevant renewals will be taken.
32.	Is there a secure location for storage of HW with proper signage?	Yes		All wastes are stored in sealed containers for a period less than 90 days. Common BW storage area is located a separate premise away from critical installation and movements.	The compliance for this practice will be ensured.
	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: IMAGE	It's a comprehensive facility run and maintained by Indian Medical Association Kerala. The facility shall be used for the entire duration of the project.
	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			Will continue to maintain the register with frequent reviews to be done by assigned staff



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		<p>Computer monitors, CPUs, and keyboards</p> <p>Printers</p> <p>Televisions</p> <p>Phone batteries (cordless and cell phone)</p> <p>Computer, tool, camera, and toy batteries</p> <p>Household batteries (all sizes)</p> <p>Batteries with lead acid, such as car batteries</p> <p>Rechargeable batteries</p>	Waste management Committee is authorized to take necessary action based on Pollution Control Board norms MCC works closely with Clean Kerala mission for e-waste disposal
36	Has the grantee obtained SPCB authorization on e-waste?	Yes		Registered under Kerala pollution control board with consent no- PCB/HO/KNR/ICO-R/1/2020 Valid up to 30.11.2024 to operate and BMW authorization under Orange category.	Timely renewals and approvals will be taken. All e-waste will be handed over to the authorized recycler choose from a proper tender system for proper recycle, reuse and destruction.
37	Does the grantee channelize the e-waste to authorized recycling or disposal facility?	yes		<p>The Hospital Condemnation Committee handles the disposal of e-waste and battery waste.</p> <p>The disposal is done through the tendering process.</p>	This practice shall be continued with proper and timely renewals of tenders.
38	Does the manufacturing grantee have Extended Producer Responsibility system and EPR-authorization in place?		NO	Describe:	This will be taken care of with proper authorization as and when need arises during the Project.
39	Does the grantee practice reduction in the usage of hazardous substances in the		NO		This will be taken care of with proper process in place as and



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	manufacture of electrical and electronic equipment and its parts?				when need arises during the Project.
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		Proper documentation will be done as and when need arises during the Project.
41	Does the grantee maintain a record of collection, storage, sale and transport of e-waste?	Yes		Engineering & Maintenance department maintains all record of collection, storage and transport of e waste.	Will continue to maintain the records with scheduled reviews and will update the records as per the e-waste guidelines.
42	Does the grantee submit annual reports on e-waste to SPCB?	yes		Annual reports on e-waste is being submitted to KPCB	This will be done regularly adhering to the timelines provided by the KPCB.
43	Is there accident reporting and records in place?	yes		The adverse /untoward incidents occurring in the hospital are reported through the On-Line Incident Reporting System that are reviewed by the Patient safety committee.	There is separate committee to monitor patient safety in the institution. In addition, there is a clinicians meeting process too
44	Are PPEs available to staff?	Yes		Necessary PPEs are available in stock for the staff adequately	The stock status of PPE will be regularly monitored and procurement will be done in time to avoid any situation of stock out. The e-wastes will be collected will be outsourced for its disposal by the Hospital Condemnation Cell complying with the proper process as per norms.
45	Is the grantee involved in manufacture of batteries?		NO		This is not applicable to us.
46	Does the grantee generate battery waste?	YES		Generated through the inverters, and equipments	Proper monitoring of generation and disposal of the battery waste shall be ensured. This will be maintained, reviewed and referenced as per norms.

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47	Does the grantee deposit the battery waste to registered recycler/dealer/manufacturer/reconditioner/collection center?	YES		The Hospital Condemnation Committee AND Hospital Waste Management Committee shall handle the disposal of e. waste and battery waste. The disposal is done through the tendering process.	Waste Management Committee is authorized to take necessary steps
48	In case of manufacturing, does the grantee comply to Battery Management Rules 2000 and ensure collection of old batteries?		NA		As we are not involved in manufacturing of Batteries, 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)		NO	Authorized vendor transport the hazardous material from MCC once every day.	This practice will be followed throughout the Project.
50	Emergency preparedness and participation of local authorities and potentially affected communities	Yes		Fire alarms and smoke detectors Fire extinguishers are placed in the entire hospital premises. Emergency escape path to the outside of the building is available in the on each floor of every building. In case of any spillages, the HIS will be informed as per protocol, and remedial measures including decontamination of spillage site will be immediately undertaken. We do not anticipate any adverse impact to either personnel or the environment.	The local community health workers and community leaders will be informed about any issues that can affect the community. The Emergency Preparedness plan will be executed as per the SOP in place
Other					
	Area of Risk	Yes	No	Details	Proposed Plan
51.	Does the grantee use any radioactive materials (isotopes)	Yes		Radiation equipment and isotopes for oncology	These will be monitored regularly as per norms.



	tracers, radiation equipment, etc)?			radiation therapy	
	Does the grantee have appropriate radioactive material and waste storage and disposal system in place?	Yes		The Radioactive waste from the laboratories is disposed off-through delay tank per regulations of the Atomic Energy Regulatory Board (AERB)	A review of the norms being followed shall be done.
	Are radioactive warning signs in place?	Yes		Radioactive warning signs provided - Bilingualism (English & Malayalam)	AERB and BARC norms will be followed. Radiation Safety Committee is in place
52.	Is the lab/room air regularly checked for microbial contamination?	Yes		Air quality will be checked periodically as per norms	Air purity test at particular point through NABL Lab
53.	Are there any odor control measures in place?	Yes		Air quality will be checked periodically as per norms	Surveillance will continue on regular basis.
54.	Are fume hoods and exhausts regularly checked and maintained?	Yes		Hepa filters of fume hoods are replaced in every six months Filters cleaning and replacing regularly Conducted periodic validation for hepa filters	Periodic maintenance, cleaning and checks will be done
55.	Does the grantee use DG set > 15 KVA?	Yes		Consent from Kerala pollution control board	Monitoring shall be done Renewal of consents timely from statutory bodies
	Does the grantee have consent for DG > 15 KVA?				
	Are emissions from boilers and DG sets regularly monitored to be within the prescribed norms?				
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		Solid and plastic waste management is through waste management committee of the hospital. These are also segregated as per rules and disposed through proper channel (auction)	Auction yearly two times for waste disposal. Will ensure proper segregation and disposal process is being followed.

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57.	Is wastewater treated separately by the grantee? (Liquid waste from laboratory, chemicals, fluids, solvents, medium and cultures, coolants, etc.)	Yes	Types of wastewater: Bath room waste & Sewerage waste, Liquid waste from laboratory, chemicals, fluids, solvents, medium and cultures, coolants etc are treating separately Treatment of wastewater: ETP Chemical management in wastewater treatment plants:.	Will ensure regular and proper treatment as per Kerala PCB norms and existing BWM Rules, 2016
	Are there sludge management and cut off drains in place for wastewater?	Yes	We are using sludge for making biogas for cooking (sludge digester) and as manure for the agriculture activities in the campus	Additional facilities will be included in future constructions
58.	Are necessary provisions for noise cancellation in place?	Yes	Provided acoustic enclosure for Generators and compressors working areas	Ensure the noise level as per PCB norms. We will take necessary steps if a risk arises in future.
59.	Are there any settlements, water bodies, cultivated land, or any other eco-sensitive areas near the grantee's premises?	Yes	Describe: maintaining 25000 sq ft grass lawn using treated water from STP Also maintaining vegetable garden using the slurry from STP and treated water Distance from premises: in side campus	Local Self Government Body of the region and other government departments shall be involved in such instances
60.	Are there any buffers, fire vehicle routes in the grantee's premises?	Yes	There are fire vehicle routes around the buildings in campus. Provided fire movement routes and exit routes on each floor as per NABII requirements. All hospital critical areas have been adequately covered with smoke detectors. These detectors are monitored All	Fire safety norms are in place which shall be followed throughout.



			department can be addressed from the control room by a public address system. At the entrance of every floor there is a fire signal board which indicates the location of the fire.	
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