Jawaharlal Institute of Postgraduate Medical Education and Research (JIPMER)

Proposal entitled: NETWORK OF ONCOLOGY CLINICAL TRIALS INDIA (NOCI)

1. Institutional Arrangements

(i) Brief description of the proposed activity

The project involves setting up a "registry" which is a cohort of common cancers to study their outcomes and clinical trial facility at JIPMER. Infrastructure in the form of manpower and equipment will be supported by BIRAC funding.

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

	Institutional								
	Arrangement								
Are	a of Risk	Yes	No	Details	Proposed Plan				
1.	Is there a designated full-time staff for Environment Health and Safety (EHS) issues?	Yes		 Biomedical waste management Sanitary department CPWD/HITES look after sewage Hospital infection control committee (HICC) look after staff training and safety including PPE, PEP etc Fire safety officer looks after maintenance of fire safety issues 	project elements will also be covered by these committees/agencies within JIPMER and a dedicated quota of man-hours will be given for the Project and the CTN sites as required. The training to the staff is given every 6 months. E.g, in Jan to June 2019, 1000 staff (doctors,				
2.	Does the EHS staff handle the following?			EHS training for	The plan includes:				
	Occupational Health and Safety	Yes			Pre-treatment of the				
	Waste Management	Yes		management	laboratory waste,				
	List of consents and regulatory clearances	Yes		(BMWM) is done by the BMWM team.	microbiological				
	Record keeping of accidents and procedures			1.44	waste, blood				
	EHS trainings for staff	Yes		u.in/departments/biom	samples and blood				
				edical-waste-	bags unbugn				
					disinfection or sterilization on-site				
				management policy					

	Environment Management		No	followed at JIPMER is as per the Biomedical prescribed by WHO Waste Management Rules 2016 The occupational health and safety issues are covered by the HICC. The consents and clearances required Establish a Barwill be obtained by Code System for respective departments. Similarly records are maintained by the respective departments. EHS training staff is carried out by the respective departments. Regular EHS training are carried out at regularly intervals as and when any new staff joins.
	Framework compliance for Innovate in India Project			
3.	Is there a reporting structure in place regarding EHS issues?	Yes		Describe: Staff are trained to regularly followed provide reporting to respective departments for issues pertaining to their areas of work. Example: reporting structure for needle stick injury, for sewage blocks, fire related issues, spills etc. exists. The reporting structure is on the website. https://www.jipmer.ed u.in/departments/biom edical-waste-management
4.	Are regular EHS trainings provided to staff?	Yes		Frequency: As Under this project, mentioned above, all the project staff safety trainings are offered throughout the year by the respective will undergo the

					EHS training. Afterwards refresher training will be provided.				
5.	Institutional Bio-Safety Committee (IBSC)	Yes		https://www.jipmer.ed u.in/research/research- committees/institution al-bio-safety- committeeibsc	The project does not involve the use of GMOs/LMOs and rDNA. Any such activities if undertake at the institution are done with due approval from IBSC.				
6.	Ethics Committee (EC)	Yes		u.in/research/research- committees/institute- ethics-committee	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.	Area of Risk Are there Standard Operating Procedures for accidents, hazards, and other emergencies (chemical spills, heat hazards, fire hazards, radioactive hazards etc.)?		No	As described above various departments are	Display of Procedures at prominent places in the site will be ensured.				
	Are there Standard Operating Procedures for accidents, hazards, and other emergencies (chemical spills, heat hazards, fire hazards, radioactive hazards etc.)? Are the following in place?		No	As described above various departments are designated within JIPMER to look after safety issues. SOPs in place for fire hazard, spill management, hear hazard and radioactive	Display of Procedures at prominent places in the site will be ensured.				
7.	Are there Standard Operating Procedures for accidents, hazards, and other emergencies (chemical spills, heat hazards, fire hazards, radioactive hazards etc.)? Are the following in place? Chemical spill kits		No	As described above various departments are designated within JIPMER to look after safety issues. SOPs in place for fire hazard, spill management, hear hazard and radioactive hazard. # Every ward / lab areas involved in handling of	Display of Procedures at prominent places in the site will be ensured. Register will be maintained for				
7.	Are there Standard Operating Procedures for accidents, hazards, and other emergencies (chemical spills, heat hazards, fire hazards, radioactive hazards etc.)? Are the following in place? Chemical spill kits Eye wash	Yes Yes Yes	No	As described above various departments are designated within JIPMER to look after safety issues. SOPs in place for fire hazard, spill management, hear hazard and radioactive hazard. # Every ward / lab areas involved in handling of chemicals and drugs has	Display of Procedures at prominent places in the site will be ensured. Register will be maintained for accidents and				
7.	Are there Standard Operating Procedures for accidents, hazards, and other emergencies (chemical spills, heat hazards, fire hazards, radioactive hazards etc.)? Are the following in place? Chemical spill kits Eye wash Shower stations	Yes Yes Yes Yes Yes#	No	As described above various departments are designated within JIPMER to look after safety issues. SOPs in place for fire hazard, spill management, hear hazard and radioactive hazard. # Every ward / lab areas involved in handling of chemicals and drugs has access to bathrooms.	Display of Procedures at prominent places in the site will be ensured. Register will be maintained for accidents and injuries in work				
7.	Are there Standard Operating Procedures for accidents, hazards, and other emergencies (chemical spills, heat hazards, fire hazards, radioactive hazards etc.)? Are the following in place? Chemical spill kits Eye wash Shower stations First Aid Kit	Yes Yes Yes Yes Yes# Yes	No	As described above various departments are designated within JIPMER to look after safety issues. SOPs in place for fire hazard, spill management, hear hazard and radioactive hazard. # Every ward / lab areas involved in handling of chemicals and drugs has access to bathrooms. Fire extinguisher details	Display of Procedures at prominent places in the site will be ensured. Register will be maintained for accidents and injuries in work areas				
7.	Are there Standard Operating Procedures for accidents, hazards, and other emergencies (chemical spills, heat hazards, fire hazards, radioactive hazards etc.)? Are the following in place? Chemical spill kits Eye wash Shower stations	Yes Yes Yes Yes Yes#	No	As described above various departments are designated within JIPMER to look after safety issues. SOPs in place for fire hazard, spill management, hear hazard and radioactive hazard. # Every ward / lab areas involved in handling of chemicals and drugs has access to bathrooms.	Display of Procedures at prominent places in the site will be ensured. Register will be maintained for accidents and injuries in work sareas				

9.	Are proper signage and storage system in place? Display of Material Safety Data	Yes	Standard signage systems in These would be regularly place at all areas. MSDS updated/ replaced. displayed wherever relevant
	Sheet (MSDS) where relevant Display of emergency numbers and procedures (Person to Contact, Doctor, Ambulance, Fire Emergency, Police) displayed in all critical	yes	Emergency numbers displayed Flammable materials stored appropriately.
	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: Fire alarms and sprinkler Any incident or audit facility in all hospital findings are handled by buildings. This is maintained by the fire safety officer. JIPMER has Fire Safety Preparedness Committee (FSPC) in place which conducts monthly meetings.
11.	Are there control measures for VOC, air emissions, high operating temperatures, pathogens/vectors etc. in place?	Yes	JIPMER follows quality Monthly meetings are control within various held every month to departments. https://jipmer.edu.in/about-us/quality-and-safety/jipmer-quality-council
12.	Are regular mock drills conducted for emergency preparedness and safety?	Yes	Frequency (type wise): Fire drills once in 6 months Disaster response drills: once a year This will be followed as per the schedule.
13.	Are staff provided with OHS training?	Yes	Describe: The following areas are covered for all staff- fire safety For staff working in specific areas the following are covered: - Chemical handling - Spill management - Needle stick prevention and response - Vaccinations required We will provide for all staff recruited in the annual project and include in the annual plan.

	Bi	iome	dica	l Waste (BMW)	
	Area of Risk	Yes	No	Details	Proposed Plan
14.	Is there generation of biomedical	Yes		•	These will be treated as
	waste (as described in Bio-Medical			Placenta, Dead Fetus,	F
	Waste Management Rules, 2016) in			Umbilical Cord, Organs, Body	_
	the grantee?			parts from OT, Amputated	
				limb. Animal body parts,	
				organs, tissues from animal	
				house. – Soiled cotton, pad,	
				dressing materials and plasters.	
				All used mask, plastic apron,	
				head cap and leggings. Used	
				HIV kits. – Blood Bag. –	
				Discarded, linen, mattresses,	
				beddings, contaminated with	
				blood. ¬ Discarded medicine &	
				cytotoxic drugs. – Dry	
				chemical wastes. Lab	
				cultures, stocks, residual toxins,	
				dishes and devices used for	
				culture.	
				Red: All plastics & rubber	
				items. — IV sets, plastic IV	
				bottle, Syringes without needle,	
				needle caps, gloves. — Blood	
				sets, corrugated drains, Uro	
				bag. — All Tubings - ET Tube,	
				Ryle's Tube and drainage tubes.	
				All catheters – urinary,	
				suction, cardiac sheath. ¬ ICD	
				bottles – romovac, all plastic bottles.	
				White: All Sharp items •	
				Needles. • Scalpel • All types of	
				Blades • Lancet. • LP needle •	
				Venflon stilette • Destroy	
				needle tip using needle	
				destroyer	
				Blue : All Glass items ¬	
				Penicillin bottles – All glass	
				bottles [Solution bottle, syrup	
				bottle, IV bottles] ¬ Used vials.	
				¬ Broken ampoules ¬ Metallic	

			implants ¬ Glass test tube, slides, cover slips. Black: ¬ All noninfectious general waste. ¬ Kitchen waste, tea cups and food waste. ¬ All covers, wrapper, paper, empty boxes and office waste. ¬ Covers of blade and suture materials.	
15.	Is there trained staff to handle biomedical waste in the grantee?	Yes	There is a department with an officer who is trained to look after BMWM. There are doctors and nurses in the team.	ongoing process.
16.	Has the grantee obtained authorization from State Pollution Control Board /Pollution Control Committee?	Yes	pollution control board: Authorization number: No:1/PPCC/BMWM/AUTHO/ JSA (PPCC/ 2018/831 dated 04/10/2018 valid upto October 2021)	
17.	Is the biomedical waste segregated at point of generation in the facility and stored in suitable containers?	Yes	Yellow Red White Blue	These will be treated as per the Bio-Medical Waste Management Rules, 2016.
18.	Is the bar code system for the segregated waste in place?	Yes	Bar-Code System is present for bags or containers containing bio-medical waste for disposal.	regularly updated as per
19.	Is the biomedical waste being sent to an authorized common BMW facility?	Yes	Name and address -M/S Solid Waste Management, Thuthipet	The vendor's contract shall be renewed on time to ensure this practice is being followed.
20.	Does the grantee have an inhouse BMW treatment facility?	No	It is outsourced. Name and address of	The facility being outsourced will treat the
	Is the treatment facility own (individual)?	No	facility: M/S Solid Waste	BMW as per the BMW Rules 2016. This

	Is the treatment facility a shared facility in an industrial park?	No	The facility is stand alone and	practice will be continued throughout the project.
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		Compliance calendar shall be maintained.
22.	Is the liquid waste checked for active cells before sending to treatment plant?	Yes		Routine checks will be done.
23.	Are necessary waste pre-treatment equipment in place?	Yes	(autoclaves, shredders,	Regular monitoring shall be undertaken.
	Do the equipment adhere to prescribed norms by State Pollution Control Board (SPCB)?	Yes	incinerators, etc.): Autoclaving and microwaves are available for pretreatment Incineration is not done in JIPMER. It is outsourced Details of waste pretreatment: Yellow waste: Segregated and handed over to outsourced facility for disposal No Pre treatement with autoclaving and microwaving as per the BMW rules 2016 Red: No pretreatment is done. Handed over to outsourced agency Sharps (White) puncture proof box. No pretreatment prior to disposal Blue: Handed over to	

				outsourced facility, NO pre-treatment in JIPMER	
				All equipment used in JIPMER conforms to pollution control	
				norms. Appropriate certification obtained from Board.	
24.	Are chlorinated plastic gloves and bags phased out by the grantee?	Yes		It has been phased out from all purchases being followed by JIPMER	
25.	Are grantee's personnel involved in handling BMW provided with regular training?	Yes		is recruited	This will be a regular process during the project.
				Trainer: Corresponding department personnel	
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		Regular check-up done in 6 months and also whenever a new employee joins or is replaced. Immunization is	This practice shall be continued ensuring immunization to all the personnel involved in the BMW.
27.	Is a daily register for biomedical waste maintained including accident reporting record?	Yes		Records are in place to document and report any accidents.	Systems already in place will be maintained.
28.	Are annual reports on BWM submitted to SPCB as per required form (see Bio-Medical Waste Rules 2016)?	Yes		https://www.jipmer.edu.in/depa	This practice would be followed ensuring submission within timelines.
	Haza	rdou	s Wa	aste (HW)	
	Area of Risk	Yes	No	Details	Proposed Plan
29.	Is there generation of hazardous waste (as per Hazardous Waste Rules,	Yes		list of hazardous waste produced in the facility	Disposal as per BMWM rules https://www.jipmer.edu.i
	2016) in the grantee?			Patient material Unused medicines Radioactive material Chemicals used in laboratories	n/departments/biomedic al-waste-management
30.	Is there trained staff in the facility to identify and handle hazardous waste?	Yes			Training is a continuous process to all employees.
	1	1	<u> </u>	1	<u> </u>

31.	Does the grantee have authorization from SPCB for hazardous waste?	Yes		Authorization from State pollution control board: Authorization number: No:1/PPCC/BMWM/AUTHO/ JSA (PPCC/ 2018/831 dated 04/10/2018 valid upto October	Timely renewals will be done and approvals will be taken.
32.	Is there a secure location for storage of HW with proper signage? Are hazardous waste stored for more than 90 days in the grantee's premises?	Yes	No	Currently all HW are treated according to guidelines and handed over to outsourced facility for disposal. Nuclear medicine department handles the waste generated from radioactive materials and these are disposed in proper manner after ensuring safe fall off of radioactivity. They have delay tanks for these items Patient material infectious material are segregated at source and disposed through external agency for proper disposal. PPE is available for personnel handling these kind of waste materials. Same precautions are followed by microbiology lab which also deals with this kind of materials. Unused medicines especially chemotherapy etc. are put in covers labelled biohazard and again sent to the external agency for destruction. Chemicals used in labs are disposed in a timely manner. No material is stored for more than 90 days. Appropriate labeling and demarcation of these items is done to ensure proper precautions when handling these items	maintained with proper

33.	Is the hazardous being send to an	Yes		Name and address of Will ensure that this
	authorized disposal facility or			facility: facility is in place with
	user?			M/S Solid Waste timely renewals of
	Is the disposal facility in house?		No	Management, Thuthipet existing vendor's
	Is the disposal facility external/outsourced?	Yes		contract.
34.	Is a register maintained on	Yes		Register maintained only forWill continue to
	production and treatment, and a			production. maintain the register
	manifest system followed for			with frequent review and
	transport of hazardous waste			updates.
	from the grantee to treatment			
	facility?			

	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		E waste is generated but there is no manufacture of electronic and electrical equipment in the premises	will be collected	
36.	Has the grantee obtained SPCB authorization on e-waste?		No		Will continue this activity throughout the project with the recycler/disposal facility stated below.	
37.	Does the grantee channelize the e-waste to authorized recycling or disposal facility?	Yes		Name and address of disposal facility/ recycler: Outsourced Facility: The e-waste generated is collected centrally including batteries etc. and then an annual tender is done to identify a proper disposal agent who collects these materials and takes them for disposal. Tender document for 2020 is available at:	This will be followed and updated regularly as and when the vendor changes, through the project.	

			I	https://immon.cdu.im/cites/d	
				https://jipmer.edu.in/sites/default/files/Tender%20Doc	
				%202020.pdf	
				<u>70202020.pd1</u>	
38.	Does the manufacturing grantee		No	Describe: Since the e waste	
	have Extended Producer			is currently handed over to	
	Responsibility system and EPR-			a proper disposal agent.	
	authorization in place?			a proper disposar agenti	
20					
39.	Does the grantee practice reduction		No	JIPMER is not involved in	
	in the usage of hazardous substances in the manufacture of electrical and			the manufacture of these	
	electronic equipment and its parts?			items	
	creetronic equipment and its parts:				
40.	Does the grantee provide detailed		No	JIPMER is not involved in	
	information on the constituents of			the manufacture of these	
	the equipment and their			items	
	components/spares and declaration				
	of conformation to Reduction in				
	Hazardous Substances in the product user documentation?				
41.	Does the grantee maintain a	Yes		Record of collection, storage of	This record will be
71.	record of collection,	168		e-waste is available.	updated and maintained
	storage, sale and transport			c-waste is available.	regularly.
	of e-waste?				regularly.
42.	Does the grantee submit annual		No		Will follow this process
	reports on e-waste to SPCB?				in future, if needed.
43.	Is there accident reporting and	Yes		Records are in place to	Activities under the
	records in place?			document and report any	project will also be
				accidents within the laboratory.	
44.	Are PPEs available to staff?	Yes		This is taken care by the	The stock status of PPE
				Hospital infection control	
				committee and the Biomedical	monitored and
				waste management department	procurement will be
				_	done in time to avoid any
					situation of stock out.
45.	Is the grantee involved in		No		
1.6	manufacture of batteries?	X 7			mi
46	Does the grantee generate battery waste?	Yes		_	The e-wastes will be
	waste:			outsourced.	collected and isolated
					within the premises of
					center. An appropriate
					agency will be
1					outsourced for disposal

					of e-wastes.
47	Does the grantee deposit the battery waste to registered recycler/dealer/manufacturer/recond itioner/collection center?		No	Name and address of battery waste receiving entity:	These details are being worked out.
48.	In case of manufacturing, does the grantee comply to Battery Management Rules 2000 and ensure collection of old batteries?		No	Not involved in manufacturing	
	Community Health and Safety and risk mitigation				
		Yes	No	Details	Proposed Plan
49	Safety Transportation Management System (for transport Of hazardous material)	Yes		This is being handed over to authorized disposal agent who is in charge of the transport of these materials who follows standard norms	the project activities along with ensuring the
50.	Emergency preparedness and participation of local authorities and potentially affected communities	Yes		This is being handed over to authorized disposal agent who is in charge of the transport of these materials who follows standard norms	followed by JIPMER.

Other					
	Area of Risk	Yes	No	Details	Proposed Plan
51	Does the grantee use any radioactive materials (isotopes tracers, radiation equipment, etc)?		No	There are departments of Radiation oncology and Nuclear medicine within JIPMER who handle radioactive substances. They follow norms laid down by government. There is a designated radiation safety officer within JIPMER/.	
	Does the grantee have appropriate radioactive material and waste storage and disposal system in place?	Yes		Describe: The radioactive material in the department of radiotherapy (cesium source, cobalt source) are handed over back to the BARC following appropriate norms laid down by the Atomic Energy Agency. There is a designated	

			Radiation afety officer in
			JIPMER who looks after these issues.
	Are radioactive warning signs in place?	Yes	In the department of These would be regularly radiotherapy and in theupdated/replaced. department of nuclear medicine
52.	Is the lab/room air regularly checked for microbial contamination?	Yes	Monitored by Hospital Surveillance wil Infection control committee continue on regula (HICC) basis.
53	Are there any odor control measures in place?	Yes	Biosafety cabinets are used Periodic cleaning will be wherever potentially toxic done. fumes are used
54.	Are fume hoods and exhausts regularly checked and maintained?	Yes	Biosafety cabinets are used Preventive maintenance wherever potential toxic fumes plan will be put in place are used- all equipments covered by AMCs in JIPMER
55.	Does the grantee use DG set > 15 KVA?	Yes	DG sets are used within Will ensure maintenance JIPMER and are maintained by of the DG sets used in
	Does the grantee have consent for DG > 15 KVA?	Yes	the Electrical Department of JIPMER.
	Are emissions from boilers and DG sets regularly monitored to be within the prescribed norms?	Yes	The Central Public Works Department which has an office campus within JIPMER campus. No DG set use is planned for this project
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	There is proper process. These It will be ensured that are also segregated as persegregation rules are rules. followed.
57.	Is wastewater treated separately by the grantee? (Liquid waste from laboratory, chemicals, fluids, solvents, medium and cultures, coolants, etc.)	Yes	There is a separate treatment plant. Lab wastes are also done and the treatment plant shall be manner. Periodic checks will be done and the treatment plant shall be maintained.
	Are there sludge management and cut off drains in place for wastewater?	Yes	The CPWD housed within in These will be JIPMER campus manages periodically checked and waste water treatment processes maintained to ensure within JIPMER. their proper functioning.
58.	Are necessary provisions for noise cancellation in place?	Yes	Describe: Very few high noise Will keep reviewing the producing equipment is used noise generated and cap

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				in the hospital premises. them according to the Wherever needed, noise cancellation headphones are provided to the employees. The DG sets etc used within JIPMER are of low noise producing variety.
59.	Are there any settlements, water bodies, cultivated land, or any other eco-sensitive areas near the grantee's premises?		No	
60.	Are there any buffers, fire vehicle routes in the grantee's premises?	Yes		There is a fire preparedness Any new buildings committee with a designated constructed within the Fire safety Officer (Dreampus are also cleared Guanseelan, HOD, Radiation for fire safety including Oncology). He ensures that the vehicle routes. fire safety norms are followed

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