Front end acquisition hardware and signal conditioning technology solutions for Minimally Invasive Fusion Imaging Endoscopy for Laparoscopic surgeries and other spin-offs

Irillic Pvt Ltd. And CMR University

Environmental and Health Risk Management Plan

1. Institutional Arrangements

Requirements	Current Status	Mitigation Steps
Institutional Bio-Safety Committee (IBSC)	Current operations of Irillic do not generate any significant bio-safety issues, hence IBSC is not yet active.	Nominated a advisor (Dr. Bopanna) for providing guidance on Bio-safety measures.
EHS Team	We have a 2-member EHS team to oversee and develop company's EHS policy.	Compliance with EHS norms.
Documentation and Record Keeping in reference to the risks mentioned below and quantifiable records of generated waste and compliance measures.	SOPs are being developed to address compliance, monitoring and record-keeping.	Maintenance of proper records and compliance with existing and updated norms.
SOPs related to Environment Compliance e.g Chemical spillage handling, waste segregation etc. '	SOPs are being developed to address compliance, monitoring and record-keeping.	Maintenance of proper records and compliance with existing and updated norms.
General Safety and Storage	Will be defined as part of SOPs.	Maintenance of proper records and compliance with existing and updated norms.

2. Environmental Impact and risk mitigation

Risks	Project Specific Risk	Potential Impact	Mitigation Steps
Air Pollution	Very low. No specific gaseous emissions, only	Negligible.	Air-conditioning is used minimally and use environment-friendly

	use of air conditioners in the facility. Environment-friendly UPS is the first line of backup. Use of back-up diesel generators when required.		R410a or R32 based refrigerants only. Work will be arranged in shifts if use of generators is necessitated on a regular basis.
Water Pollution and Waste water treatment	Very low. Water is used only for drinking, housekeeping and for rest-room usage.	Minimal.	The disposal of sewage water is via Bangalore Corporation (BBMP) sewage management system. Compliance with local Pollution control board regulations will be ensured.
Chemical waste (including signage, storage and SOP for spillage)	Negligible. Chemical materials are not used during design & development of the product; therefore, no chemical waste is generated.	None.	Prototyping activities that use harmful chemicals will be outsourced to ISO 13485 compliant vendors.
Biological Waste	No biological materials (e.g. blood, tissue, etc) are generated at Irillic facility. All clinical trials are done at hospital site(s).	Contamination at clinical trial hospital site(s).	Clinical trials will be done at hospitals equipped with bio waste management procedures.
Heavy metals	Moderate. Electronic equipment may use heavy metals in circuit boards, wires and magnets etc.	Heavy metal pollution of the environment due to fine metallic particles.	All electronics subsystems will be designed for RoHS compliance, including use of lead-free solder. All fabricated material is of mild-steel, aluminium and steel. Hence, no heavy metals are used.
Electronic Waste	Moderate. Un-repairable, Obsolete or End-	Leeching of metals into the environment, along with	We have identified two authorized re-cyclers in Bangalore for disposing e-waste. Design

	of-Life electronic assemblies	associated plastics.	iterations will be performed online to reduce waste from prototypes.
Radiation Waste	None. Radioactive materials are not used during design & development of the product.	Not applicable.	Not applicable. In practice, our proposed product enables hospitals to replace radioactive products (e.g. gamma probe).
Destruction/ alteration of surrounding ecosystem	Negligible. Our process involves design & assembly of electronics parts & accessories. Additionally, it involves software development with server computing environment located in Cloud. This enables us to operate with a very low-energy-usage footprint.	Negligible.	There are no harmful emissions or noise emissions into the environment due to our activities. Thereby, there are no significant factors affecting the surrounding ecosystem.
Construction	None. Current plan is to use ready-to-occupy buildings; new constructions are not envisaged in the next 2 years..	Construction activities are not in our plan. Hence, Not applicable	Our facility is fully built-up, no additional construction activity is done. Hence, Not applicable.

3. **Occupational Health and Safety and risk mitigation**

Risks	Project Specific Risk	Potential Impact	Mitigation Steps
Heat Hazards	Negligible risk (no equipment in facility that generate hazardous heat other than soldering iron)	Potential for fire and burn injuries due to flammable material in the vicinity	Electronic Soldering is done by trained personnel in a designated area only. Our personnel are trained on emergency preparedness during fire.
Chemical hazards,	Negligible. Chemical	None.	Prototyping activities that use harmful chemicals will

including fire and explosions	materials are not used during design & development of the product; therefore, there is no chemical hazard.		be outsourced to ISO 13485 compliant vendors.
Pathogenic and biological hazards	No biological materials (e.g. blood, tissue, etc) are generated at Irillic facility. All clinical trials are done at hospital site(s). Hence there are no pathogenic and biological hazards.	Contamination at clinical trial hospital site(s).	Clinical trials will be done at hospitals equipped with bio waste management procedures.
Radiological hazards	Minimal risk during EMI/EMC testing. Radioactive materials are not used during design & development of the product.	Minimal risk during EMI/EMC testing.	Reference test equipment (EMI/EMC) are used only at NABL certified labs and not at Irillic site.
Noise	Minimal risk. Our process involves design & assembly of electronics parts & accessories. Additionally, it involves software development with server computing environment located in Cloud).	Minimal. No noise-generating processes are required in the proposed work at our site.	• Low-db Air conditioner used in Lab/Assembly area • Metal enclosure fabrication is done at vendor sites located in industrial zone(s)
Process safety	Moderate risk. Assembly of prototypes for clinical trials should be done correctly.	Incorrect assembly may adversely affect the clinical subject due to malfunction of the equipment.	All components and equipment undergo QC checks at various stages of fabrication and assembly process. Employees are trained on Safety guidelines to minimize the risk.
others	Moderate risk.	Damage to eyesight/ loss of	Employees are trained on the importance and use of safety glasses when testing

	Inadvertent direct eye exposure to laser modules	vision or laser burns on skin.	laser subsystems. Personal protective equipment is provided.

4. Community Health and Safety and risk mitigation

Risks	**Project Specific Risk**	**Potential Impact**	**Mitigation Steps**
Safety Transportation Management System (for transport of hazardous material)	Negligible. We do not use or transport any hazardous material.	Negligible	We do not use or transport any hazardous (chemical, radiological or biological) material.
Emergency preparedness and participation of local authorities and potentially affected communities	Minimal risk. As the facility does not use any hazardous material, the major risk of emergency is accidental.	Accidental fire is the major concern – due to electrical problems – leading to damage to property, life and the environment.	Our personnel are trained on emergency preparedness during fire. Accordingly, fire safety equipment and smoke alarms are in place. Facility is also equipped with multiple alternate exits. We plan to have electrical safety audits. We do not store any flammable material in our facility.
In case your organization already has **EHS guideline**, please summarise the same. If not, please describe the impact because of hazardous material, release of chemicals, biologicals, management of catastrophic events like fire/explosion**.**			

Clinical Trial Risk Management Plan (if applicable)

Clinical and Regulatory		
Area of Risk	**Monitoring Parameters**	**Mitigation Measures**
Production of CT material	Study Protocol, investigator's brochure, consent forms, case report forms, equipment	Irillic has experience in designing studies for surgical imaging system and

	prototypes, etc will be generated by Irillic along with Principal Investigator (PI) for all necessary protocols. The prototype equipment for testing will be certified by QA/ QC of Irillic Pvt. Ltd.	guidance from PI who has done CT for Irillic products.
Protocol design and scientific validity ensuring Favourable risk-benefit ratio	For each protocol necessary for CT, multiple primary and secondary outcomes will be listed to ensure favourable risk-benefit ratio. Since studies of similar nature has been conducted in US and Europe previously yielding positive results, Irillic will take reference from such studies.	Protocol will be designed along with Principal Investigator who will be an expert in the specific surgical field and will be verified, reviewed and approved by the IEC. Protocols will be designed after taking reference from similar studies done in the US.
Regulatory approvals	Not applicable (not a notified device under CDSCO).	Since predicate devices are available in the market, regulatory approvals will be achieved based on predicate devices. If the device is notified at the time of study, appropriate approvals will be taken.
Ethics approvals	All material and literature for ethics committee approval will be developed along with Principal Investigator.	Irillic has experience in working with PI and Ethics committee before and successfully completing CT without any Ethical violation.
Ensuring appropriate informed consent process and respect for human subjects	Appropriate Informed Consent will be generated for the study by the Sponsor and PI and given to the Clinical Research (or equivalent) dept of the Study Centre.	Clinical protocol will require study centre to take IC for each patient before initiating procedure. This will be handled by the Clinical Research (or equivalent) Dept of the concerned study centre.
Capacity of the sponsor	Sponsor will provide equipment, support and training during the trial duration	Ongoing support during clinical trials
Staff at the trial site and Investigator responsibilities	Trained clinical support personnel from Irillic will be present for the study as required.	Multiple clinical support personnel will be trained for the study to ensure

		uninterrupted support during the study. Surgeons will also be trained to use the system along with all necessary protocols before initiating the study.
Recruitment of study subjects and fair subject selection	Only patients with concerned illness already scheduled for surgery will be required for the study with necessary consent taken.	Study will be conducted at high patient volume centres. Strict inclusion and exclusion criteria will be followed by the PI and Clinical Research team. As per Clinical Trials agreement
Safety Management (AE and SAE)	AE and SAE occurrence very unlikely since device is an imaging device only. Clinical team will be available on-hand (as part of post-operative care) to monitor AE/ SAE related to the device in any way.	FDA-approved dye ICG contra-indications are used as a guide to avoid dye related adverse events. Study will be conducted at a centre which already has alternate laparoscopy system (without fusion imaging) and trained surgeons who can continue to conduct the surgery in case of any issue with the Irillic system The device itself is a imaging-only system with negligible risk of causing adverse events.
Costs and reimbursements to subjects	Subjects who are scheduled for surgery during normal course, will be recruited for the study. Charges/reimbursements (if any) to be determined in consultation with partner hospital(s)	Not Applicable
Compensation and Insurance	Liability Claims (if any) received under the study.	Claim will be verified for study protocol compliance. Insurance & associated claims as per Clinical Trial Liability Insurance Policy will be processed.
Breach of confidentiality and protocol violations	Protocol will be monitored by the PI and Clinical Research Dept along with Irillic.	Clinical Research Dept will be submitting regular reports to the Ethics committee to ensure proper procedures are followed for

		patient selection, consent forms, protocols etc. Study data captured using access-controlled software application/ data-base
Audit and independent reviews	Study data will be captured on an access-controlled data-base which can be accessed only by authorized personnel from the investigator team and Irillic.	Periodic data review will be done by PI's Clinical Research Dept.
Logistics and Data quality	Case Report Form will be designed & finalized with the PI before initiating the study.	Training will be provided to all data entry personnel before starting the study to ensure proper data entry process is followed.
Serology / efficacy	Proposed product does not involve use of blood serum and other body fluids; hence, Not Applicable	Not Applicable
Post- trial access issues (if applicable)	Post-trial study data will be archived in an access-controlled database/ folder. This information is primarily related to imaging – both still images and short videos.	Agreement with the clinical research team for archiving of all data related to clinical study.

CMR University

Environmental and Health Risk Management Plan

1. Institutional Arrangements

Requirements	Current Status	Mitigation Steps
Institutional Bio-Safety Committee (IBSC)	The Institute has an understanding with the Partner where such experiments are required to be conducted which could involve any BIO Safety issues , shall be conducted by Irillic Private Limited, which is the main execution partner in this project. The collaboration involves first the study phase and another joint development of Proof of Concept. Hence all the POC construction is done by Irillic.	
EHS Team		
Documentation and Record Keeping in reference to the risks mentioned below and quantifiable records of generated waste and compliance measures.		
SOPs related to Environment Compliance e.g Chemical spillage handling, waste segregation etc. '		
General Safety and Storage		

2. Environmental Impact and risk mitigation

Risks	Project Specific Risk	Potential Impact	Mitigation Steps
Air Pollution	minimal risk	No specific equipment are used which causes Air Pollution	No specific equipment are used which causes Air Pollution
Water Pollution and Waste water treatment	minimal risk	No specific equipment are used which causes water Pollution	No specific equipment are used which causes water Pollution
Chemical waste (including signage, storage and SOP for spillage)	minimal risk	No Chemicals are used	No Chemicals are used
Biological Waste	Minimal risk	No biological materials (e.g. blood, tissue, etc) are part of our activities	Clinical trials are undertaken by Irillic to be done at hospitals equipped

			with bio waste management procedures
Heavy metals	minimal risk	All electronics subsystems will be designed for RoHS compliance, including use of lead-free solder. All fabricated material are of mild-steel, aluminium and steel. Hence, no heavy metals are used.	All electronics subsystems will be designed for RoHS compliance, including use of lead-free solder. All fabricated material are of mild-steel, aluminium and steel. Hence, no heavy metals are used.
Electronic Waste	minimal risk	Un-repairable, Obsolete or End-of-Life electronic assemblies	We have identified two authorized re-cyclers in Bangalore for disposing e-waste. Design iterations will be performed online to reduce waste from prototypes.
Radiation Waste	Minimal risk	Radioactive materials are not used during design & development of the product. In practice, our proposed product enables hospitals to replace radioactive products (e.g. gamma probe).	Radioactive materials are not used during design & development of the product. In practice, our proposed product enables hospitals to replace radioactive products (e.g. gamma probe).
Destruction/ alteration of surrounding ecosystem	Minimal risk	No activity of this nature is carried out CMRU has adequate physical infrastructure to carry out this project.	No activity of this nature is carried out
Construction			CMRU has adequate physical infrastructure to carry out this project.

3. Occupational Health and Safety and risk mitigation

Risks	Project Specific Risk	Potential Impact	Mitigation Steps
Heat Hazards	minimal risk	CMRU is an educational Institution and is run as UGC guidelines	CMRU comes under the following guidelines UGC GUIDELINES ON SAFETY OF STUDENTS ON AND OFF CAMPUSES OF HIGHER EDUCATIONAL INSTITUTIONS Under this each person working in the lab or any such place is adequately trained to handle Heat Hazards. Further, Based on the guidelines all such work places are having fire and smoke detectors, along with quick access fire extinguishers.
Chemical hazards, including fire and explosions	Minimal risk	Project implementation does not envisage the use of chemical	Project implementation does not envisage the use of chemical
Pathogenic and biological hazards	. Minimal risk	No biological materials (e.g. blood, tissue, etc) are part of our activities. Hence there are no pathogenic and biological hazards.	No biological materials (e.g. blood, tissue, etc) are part of our activities. Hence there are no pathogenic and biological hazards.
Radiological hazards	minimal risk.	Radioactive materials are not used during design & development of the product. Hence there are no radiological hazards Minimal risk during EMI/EMC testing.	Radioactive materials are not used during design & development of the product. Hence there are no radiological hazards Reference test equipment (EMI/EMC) are used only at NABL certified labs and not at CMRU site.

Noise	minimal risk	We are involved in development of mechanical systems for imaging equipment. This activity would not generate noise loud enough to cause disturbance.	We are involved in development of mechanical systems for imaging equipment. This activity would not generate noise loud enough to cause disturbance.
Process safety	Negligible risk (Primarily, an electronics & software design and assembly facility, does not involve any hazardous process).	Primarily, an academia and research center, does not involve any hazardous process	Employees are trained on Safety guidelines
others	Inadvertent direct eye exposure to laser modules	Employees are trained on it's importance and use of safety glasses when testing laser subsystems	Employees are trained on it's importance and use of safety glasses when testing laser subsystems Personal protective equipment is provided.

4. Community Health and Safety and risk mitigation

Risks	**Project Specific Risk**	**Potential Impact**	**Mitigation Steps**
Safety Transportation Management System (for transport of hazardous material)	minimal risk.	Project implementation does not involve transportation of hazardous material.	Project implementation does not involve transportation of hazardous material.

Emergency preparedness and participation of local authorities and potentially affected communities	Fire accident	Damage to property and persons.	Based on UGC Guidelines, Fire preparedness training is given regularly and also fire alarm drills are conducted from time to time. (Following is the UGC guideline on this. HEIs should install a fire safety system under which mechanisms for the detection of a fire, the warning resulting from a fire and standard operating procedures for the control of fire are evolved. This may include sprinkler systems or other fire extinguishing systems, fire detection devices, stand-alone smoke alarms, devices that alert one to the presence of a fire, smoke control and reduction mechanisms and fire doors & walls that reduce the spread of a fire. Students and staff should be trained in the effective operation of firefighting devices. Mock drills for fire situation should be undertaken at least once in a semester.)
In case your organization already has **EHS guideline**, please summarise the same. If not, please describe the impact because of hazardous material, release of chemicals, biologicals, management of catastrophic events like fire/explosion**.**			

Clinical Trial Risk Management Plan (if applicable)

Since CMR University is not participating in any Clinical Trails for this project and hence not applicable.

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.