SERVICE STANDARD 26: STANDARDS FOR CLINICAL RESEARCH CENTRE

PREAMBLE

Clinical research is a branch of healthcare science that determines the safety and effectiveness (efficacy) of medications, devices, diagnostic products and treatment regimens intended for human use. These may be used for prevention, treatment, diagnosis, or for relieving symptoms of a disease. Clinical research is often conducted at academic medical centers and affiliated research study sites, i.e. hospitals. The Clinical Research Centre (CRC) is organized and administered to support and facilitate research activities in the Facility according to the goals and objectives of the Facility Clinical Research Centre (FCRC) and to meet the needs of the clients being served. The FCRC shall be directed by a person qualified in the specific services and assisted by sufficient qualified support staff to enable fulfillment of the FCRC's goals and objectives and ensure continuing education and development.

TOPIC 26.1
ORGANISATION AND MANAGEMENT

STANDARD 26.1.1

The Clinical Research Centre (CRC) is organised and administered to support and facilitate research activities in the Facility according to the goals and objectives of the Facility Clinical Research Centre (FCRC) and to meet the needs of the clients being served.

CRITERION NO.	CRITERIA FOR COMPLIANCE	SELF RATING	FACILITY COMMENTS	SURVEYOR FINDINGS		
				AREAS FOR IMPROVEMENT / RECOMMENDATIONS	SURVEYOR RATING	RISK
26.1.1.1	Vision, Mission, and values statements of the Facility are accessible. Goals and objectives that suit the scope of the Clinical Research Centre are clearly documented and measurable that indicate safety, quality, and patient-centered care. These reflect the roles and aspirations of the service and the needs of the community. These statements are monitored, reviewed, and revised as required accordingly and communicated to all staff.	NA			NA	
	EVIDENCE OF COMPLIANCE					
	1. Vision, Mission, and values statements of the Facility are available, endorsed, and dated by the Governing Body. — NA					
	2. Goals and objectives of the Clinical Research Centre in line with the Facility statements are available, endorsed and dated. — NA					
	3. Evidence of planned reviews of the above statements. — NA					
	4. These statements are communicated to all staff (orientation programme, minutes of meeting, etc) — NA					
	5. Achievement of goals and objectives are monitored, reviewed and revised accordingly. — NA					
26.1.1.2 CORE	There is an organisation chart which:	NA			NA	

	a) provides a clear representation of the structure, functions, and reporting relationships between the Person In Charge (PIC), Head, and staff of the Clinical Research Centre; b) provides a clear representation of the structure, functions, and reporting relationships between the Clinical Research Center and Hospital organization; c) is accessible to all staff and clients; d) includes off-site services if applicable; e) is revised when there is a major change in any of the following: i) organization; ii) functions; iii) reporting relationships; iv) staffing patterns. EVIDENCE OF COMPLIANCE 1. Clearly delineated current organisation chart with line of functions and reporting relationships between the Person In Charge (PIC), Head and staff of Clinical Research Centre. — NA 2. Clearly delineated current organisation chart with line of functions and reporting relationships between Clinical Research Centre and Hospital organization — NA 3. Organisation chart of the service is endorsed, dated and accessible — NA 4. The organisation chart is revised when there is a major change in any of the items (d)(i) to (iv). — NA					
26.1.1.3	Regular staff meetings are held between the Head of Service and staff with sufficient regularity to discuss issues and matters pertaining to the operations of the Facility Clinical Research Centre (FCRC). Minutes are kept; decisions and resolutions made during meetings shall be accessible, communicated to all staff of the service and implemented. EVIDENCE OF COMPLIANCE 1. Minutes are accessible, disseminated and acknowledged by the staff. — NA 2. Attendance list of members with adequate representatives of the service. — NA 3. Frequency of meetings as scheduled. — NA 4. Discussion and resolutions are implemented (Problems not solved to be brought forward in the next meeting until resolved). — NA	NA			NA	

26.1.1.4	The Head of FCRC is involved in the planning, justification and management of the budget and resource utilisation of the services. EVIDENCE OF COMPLIANCE 1. Minutes of Facility-wide management meeting — NA 2. Documented evidence on request for allocation of budget and resources (staffing, equipment, etc) for the service. — NA 3. Approved budget and resources. — NA	NA			NA	
26.1.1.5	The Head of FCRC is involved in the appointment and/OR assignment of staff. EVIDENCE OF COMPLIANCE 1. Records on staff interview (if applicable) — NA 2. Appointment/assignment letter of Head of Service — NA 3. Job description of Head of Service — NA 4. Records on staff deployment — NA 5. Duty roster — NA	NA			NA	
26.1.1.6	Appropriate statistics and records shall be maintained in relation to the provision of FCRC and used for managing the services and patient care purposes. EVIDENCE OF COMPLIANCE 1. Records are available for CRC provision but not limited to the following: a) workload (research consultation, National Medical Research Register (NMRR) Registration, research training, Hospital Research Review Committee); — NA b) staffing number and staff profile; — NA c) staff training and human resource records; — NA d) complaints and report; — NA e) research database; — NA f) data on performance improvement activities, including performance indicators. — NA	NA			NA	
26.1.1.7	Where services are obtained from an external source, there is a written agreement between the external service provider and the Facility stating the requirements for service delivery, including the following:	NA			NA	

a) formal lines of communication and responsibilities between the external service provider and the FCRC;
b) provision of adequate numbers of appropriately qualified personnel to perform their duties;
c) participation, as appropriate, of the external service provider in committees of the FCRC;
d) arrangement for adequate pickup and delivery;
e) arrangements for after-hours and emergency services;
f) mechanisms for dealing with problems in service delivery;
g) adequate facilities and equipment for providing the services at the FCRC, and at the site of the external service;
h) involvement of the external service provider in safety and performance improvement activities of the FCRC, as appropriate;
i) comply with the appropriate MSQH Standards of Accreditation for that part of the service which functions within the FCRC.
j) visits to the facilities of the external service provider by the staff of FCRC to ensure requirements of standards are met.

EVIDENCE OF COMPLIANCE		
1.	The Contract Agreement between the Facility and the external service provider(s) is in place and covers item (a) to (i).	NA
2.	Records on communication and responsibilities between the external service provider and the FCRC.	NA
3.	Record of qualified personnel to perform their duties.	NA
4.	Documentation for sample handling and transportation to external source (e.g. central laboratory in Singapore/Thailand, etc.)	NA
5.	Documentation arrangements for after-hours and emergency services, e.g. severe adverse event/drug reaction/Suspected Unexpected Serious Adverse Reaction (SUSAR) and report to relevant authority within specific time.	NA
6.	Documentation of relevant authority, e.g. research sponsor/Clinical Research Associate (CRA)/Clinical Research Organization (CRO)/Medical Research Ethics Committee (MREC) and etc for safety and performance improvement activities, e.g. monitoring of Investigator product, consent, research data and etc.	NA
7.	Records on visit to facilities of the external service provider by the staff of FCRC, e.g. if involve multi-centre study particularly Investigator Initiated Research (IIR).	NA

TOPIC 26.2
HUMAN RESOURCE DEVELOPMENT AND MANAGEMENT

STANDARD 26.2.1
The FCRC shall be directed by a person qualified in the specific services and assisted by sufficient qualified support staff (permanent/contract/study coordinator) to enable fulfillment of the FCRC's goals and objectives and ensure continuing education and development.

CRITERION NO.	CRITERIA FOR COMPLIANCE		SELF RATING	FACILITY COMMENTS	SURVEYOR FINDINGS		
					AREAS FOR IMPROVEMENT / RECOMMENDATIONS	SURVEYOR RATING	RISK
26.2.1.1 CORE	The Head and staff of the FCRC shall be individuals qualified by education, training, experience, and certification to commensurate with the requirements of the various positions.		NA			NA	
	EVIDENCE OF COMPLIANCE						
	1.	Head and all trained staff of FCRC shall have a valid professional Annual Practising Certificate (APC), privileging, and Good Clinical Practice (GCP) Certification for Intervention study and relevant certificate.	NA				
	2.	Appointment/assignment/placement letters	NA				
	3.	Experience of the head and staff meets the demands of their positions.	NA				
	4.	Deployment/assignment according to staff speciality.	NA				
	5.	Training and competency records	NA				
26.2.1.2	The authority, responsibilities, and accountabilities of the Head of FCRC are clearly delineated and documented.		NA			NA	
	EVIDENCE OF COMPLIANCE						
	1.	Appointment/assignment letter and Term of Reference for Head of FCRC from relevant authority.	NA				
	2.	Description of duties and responsibilities.	NA				
26.2.1.3	Sufficient numbers of personnel and support staff with appropriate qualifications are employed to meet the need of the FCRC.		NA			NA	
	EVIDENCE OF COMPLIANCE						
	1.	Number of staff and qualification commensurate with workload.	NA				

	2.	Staffing pattern	NA				
	3.	Duty roster	NA				
	4.	Census and statistics	NA				
26.2.1.4	There are written and dated specific job descriptions for all categories of staff that include: a) qualifications, training, experience, and certification required for the position; b) lines of authority; c) accountability, functions, and responsibilities, d) reviewed when required and when there is a major change in any of the following: i) nature and scope of work; ii) duties and responsibilities; iii) general and specific accountabilities; iv) qualifications required and privileges granted; v) staffing patterns; vi) Statutory Regulations. e) administrative and clinical functions.		NA			NA	
	EVIDENCE OF COMPLIANCE						
	1.	Updated specific job description is available for each staff that includes but not limited to as listed in (a) to (e).	NA				
	2.	Job description includes specialisation skills	NA				
	3.	Relevant privileges granted where applicable	NA				
	4.	The job description is acknowledged by the staff and signed by the Head of Service and dated.	NA				
26.2.1.5	Personnel records on training, staff development, leave and others are maintained for every staff. ***Note**: Staff personal record may be kept in Human Resource Department as per Facility policy.*		NA			NA	
	EVIDENCE OF COMPLIANCE						
	1.	Staff personal records include:					
	a)	staff biodata;	NA				
	b)	qualification and experience;	NA				
	c)	evidence of current registration;	NA				
	d)	training record;	NA				

	e)	competency record and privileging;	NA				
	f)	attendance and leave record;	NA				
	g)	confidentiality agreement.	NA				
	h)	deployment record outside hospital facility	NA				
26.2.1.6	There is a structured orientation program where new staff are briefed on their services, operational policies, and relevant aspects of the Facility to prepare them for their roles and responsibilities.			NA			NA	
	EVIDENCE OF COMPLIANCE							
	1.	Policy requiring all new staff to attend a structured orientation	NA				
	2.	Records on structured orientation programme	NA				
	3.	Orientation Brief	NA				
	4.	List of attendance	NA				
26.2.1.7	There is evidence of training needs assessment and staff development plan which provides the knowledge and skills required for staff to maintain competency in their current positions and future advancement.			NA			NA	
	EVIDENCE OF COMPLIANCE							
	1.	Training needs assessment is carried out and gaps identified.	NA				
	2.	A staff development plan based on training needs assessment is available.	NA				
	3.	Training schedule/calendar is in place.	NA				
	4.	Training module	NA				
26.2.1.8	There are continuing education activities for staff including medical practitioners to pursue professional interests and to prepare for current and future changes in practice.			NA			NA	
	EVIDENCE OF COMPLIANCE							
	1.	Training calendar includes in-house/external courses/ workshop/conferences	NA				
	2.	Contents of training programme	NA				
	3.	Training records on continuing education activities are kept and maintained for each staff including training in life.	NA				
	4.	Certificate of attendance/degree/post basic training.	NA				

26.2.1.9	Staff receive evaluation of their performance at the completion of the probationary period and annually thereafter, or as defined by the Facility. EVIDENCE OF COMPLIANCE 1. Performance appraisal for staff is completed upon probationary period and as an annual exercise. NA	NA			NA	
26.2.1.10	In a teaching Facility, the FCRC shall address the educational needs and provide teaching for undergraduates and postgraduates as determined by the Facility. EVIDENCE OF COMPLIANCE 1. Record on mentoring and relevant research training for undergraduates and postgraduates as determined by the Facility. NA 2. Memorandum of Understanding NA	NA			NA	
26.2.1.11	In Facilities which have teaching and research responsibilities, the staff of the FCRC give their cooperation or participate in the teaching and research programmes as determined by the Facility. EVIDENCE OF COMPLIANCE 1. Documentation on participation in a teaching/research training/mentoring as determined by the Facility. NA	NA			NA	
26.2.1.12	FCRC shall have arrangements for the: a) Promotion of staff well-being. b) Resolution of workplace issues. EVIDENCE OF COMPLIANCE 1. Documented procedures to promote well-being, e.g. stress management, healthy lifestyle programmes NA 2. Documented procedure to manage workplace issues. NA 3. Staff being provided with appropriate supervision, support and advice NA	NA			NA	
26.2.1.13	FCRC shall educate and support patients/ service users utilising clinical research findings to maintain and improve their own health and wellbeing. EVIDENCE OF COMPLIANCE 1. Documented communication between researcher and patient/subject on research findings (if applicable) NA	NA			NA	

	2.	Assessment of patient medical condition	NA					
	3.	Referral to relevant party(ies) for further management	NA					
	4.	Training plan on person-centred care in clinical trial by FCRC	NA					

TOPIC 26.3
POLICIES AND PROCEDURES

STANDARD 26.3.1
There are documented policies and procedures that reflect current knowledge and practice for the FCRC and are consistent with goals and objectives of the FCRC and relevant regulations and statutory requirements.

CRITERION NO.	CRITERIA FOR COMPLIANCE		SELF RATING	FACILITY COMMENTS	SURVEYOR FINDINGS		
					AREAS FOR IMPROVEMENT / RECOMMENDATIONS	SURVEYOR RATING	RISK
26.3.1.1 CORE	There are written policies and procedures for each of the services provided by FCRC which are consistent with the overall policies of the Facility, regulatory requirements and current standard practices. These policies and procedures are signed, authorised and dated. There is a mechanism for and evidence of a periodic review at least once in every three years.		NA			NA	
	EVIDENCE OF COMPLIANCE						
	1.	Documented policies and procedures for the service.	NA				
	2.	Policies and procedures are consistent with regulatory requirements and current standard practices such as International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use – Good Clinical Practice (ICH-GCP), Director General Circular on Conducting Research in Ministry of Health, Cosmetic and Drug Act, Medical Device Act, The Malaysian Code of Responsible Conduct in Research by National Science Council, Medical Research Ethics Committee (MREC), Malaysian Guidelines on the Use of Human Biological Samples for Research, Facility policies & procedures, and relevant regulations and guidelines.	NA				
	3.	Evidence of periodic review of policies and procedures.	NA				
	4.	The policies and procedures are endorsed and dated.	NA				
26.3.1.2	Policies and procedures are developed by a committee in collaboration with staff, medical practitioners, management, and where required, with other external service providers and with reference to relevant sources involved. Cross-departmental collaboration is practiced in developing relevant policies and procedures where applicable.		NA			NA	
	EVIDENCE OF COMPLIANCE						

	1.	Minutes of committee meetings on development and revision on policies and procedures.	NA				
	2.	Minutes of meetings with evidence of cross-reference with other departments, e.g., Hospital Research Committee.	NA				
	3.	Documented cross departmental policies	NA				
26.3.1.3	Current policies and procedures are communicated to all staff.			NA			NA	
	EVIDENCE OF COMPLIANCE							
	1.	Training and briefing on the current policies and procedures/Minutes of meetings	NA				
	2.	Circulation list and acknowledgement	NA				
26.3.1.4 CORE	There is evidence of compliance with policies and procedures.			NA			NA	
	EVIDENCE OF COMPLIANCE							
	1.	Compliance with policies and procedures through:					
	a)	interview of staff on practices;	NA				
	b)	verify with observation on practices;	NA				
	c)	results of audit on practices;	NA				
	d)	practices in line with established policies and procedures.	NA				
26.3.1.5	Copies of policies and procedures, protocols, guidelines, relevant Acts, Regulations, By-Laws and statutory requirements are accessible to staff.			NA			NA	
	EVIDENCE OF COMPLIANCE							
	1.	Copies of policies and procedures, protocols, guidelines, relevant Acts, Regulations, By-Laws, and statutory requirements are accessible on-site for staff reference.	NA				
26.3.1.6	The processes needed for the FCRC quality management, which are consistent with and are contributing towards the FCRC and Facility's goals and objectives shall be determined.			NA			NA	
	EVIDENCE OF COMPLIANCE							
	1.	Adequate standard process sequence and interaction of the processes provided by the FCRC.	NA				
26.3.1.7	There are written sequence and interaction of the processes provided by the FCRC.			NA			NA	

	EVIDENCE OF COMPLIANCE						
	1.	Adequate documentation on sequence and interaction of the processes provided by the FCRC.	NA				
26.3.1.8	Resources and information needed to support the monitoring and operation of these processes shall be made available.		NA			NA	
	EVIDENCE OF COMPLIANCE						
	1.	Adequate resources and information to support the monitoring and operation of these processes shall be made available.	NA				

TOPIC 26.4
FACILITIES AND EQUIPMENT

STANDARD 26.4.1
Adequate facilities and equipment are available to enable the FCRC to meet its goals and objectives.

CRITERION NO.	CRITERIA FOR COMPLIANCE		SELF RATING	FACILITY COMMENTS	SURVEYOR FINDINGS		
					AREAS FOR IMPROVEMENT / RECOMMENDATIONS	SURVEYOR RATING	RISK
26.4.1.1	There are adequate and appropriate facilities and equipment with proper utilisation of space to enable staff to carry out their professional and administrative functions.		NA			NA	
	EVIDENCE OF COMPLIANCE						
	1.	Adequate and proper utilisation of space.	NA				
	2.	Appropriate type of equipment to match the complexity of services.	NA				
	3.	Easy access and clear exit routes.	NA				
26.4.1.2	There is documented evidence that equipment complies with relevant national/international standards and current statutory requirements.		NA			NA	
	EVIDENCE OF COMPLIANCE						
	1.	Testing, commissioning and calibration records (certificates or stickers)	NA				
	2.	Certification of equipment from certified bodies, e.g. Standards and Industrial Research Institute of Malaysia (SIRIM), etc as evidence of compliance to the relevant standards and Acts.	NA				
26.4.1.3 CORE	There is evidence that the Facility has a comprehensive maintenance programme such as predictive maintenance, planned preventive maintenance, and calibration activities, to ensure the facilities and equipment are in good working order.		NA			NA	
	EVIDENCE OF COMPLIANCE						
	1.	Planned Preventive Maintenance records such as schedule, stickers, etc.	NA				
	2.	Planned Replacement Programme where applicable	NA				
	3.	Complaint records	NA				
	4.	Asset inventory	NA				

26.4.1.4	Where specialised equipment is used, there is evidence that only staff who are trained and authorised by the Facility operate such equipment.			NA			NA	
	EVIDENCE OF COMPLIANCE							
	1.	User training records	NA					
	2.	Competency assessment record	NA					
	3.	Letter of authorisation	NA					
	4.	List of staff trained and authorised to operate specialised equipment	NA					

TOPIC 26.5
SAFETY AND PERFORMANCE IMPROVEMENT ACTIVITIES

STANDARD 26.5.1
The FCRC is required to be involved in the Facility's performance improvement activities as per determined by the respective quality departments of the Facility. These performance improvement activities will be consistent with the quality objectives of the FCRC towards contributing to the quality objectives of the Facility.

CRITERION NO.	CRITERIA FOR COMPLIANCE	SELF RATING	FACILITY COMMENTS	SURVEYOR FINDINGS		
				AREAS FOR IMPROVEMENT / RECOMMENDATIONS	SURVEYOR RATING	RISK
26.5.1.1	The FCRC is required to conduct risk assessment that could be relevant to patients/service users and/or staff based on: a) Identify procedures, treatments or aspects of care that are at risk; i. Procedures in research and clinical trials ii. Laboratory activities in FCRC iii. Risks of Investigational product (IP) or medical devices incident (if applicable) iv. Risk of research misconduct involving individual or team The FCRC shall have an appropriate mitigation plan for the risks determined by the Facility.	NA			NA	
	EVIDENCE OF COMPLIANCE					
	1. Documented policies and procedures for risk assessment plan — NA					
	2. Structured mitigation plans which include:					
	a) Training of staffs — NA					
	b) Policy and procedure — NA					
	c) Reports — NA					
	d) Acknowledgement by Head of Service and PIC/Hospital Director — NA					
	e) Feedback given — NA					
26.5.1.2	Procedures in research and clinical trials, these could include (if applicable to FCRC): a) Genetic and genomic testing b) Medical and healthcare device e.g.: robotics device, 3D, applications, and etc c) Equipment and procedure risks, e.g., fire/injury, sharp injuries, and etc d) Research recruitment strategy e) Unauthorized personnel to perform research-related activities f) Unreliable research data	NA			NA	

	EVIDENCE OF COMPLIANCE						
	1.	Documented policies and procedures for risk assessment plan	NA				
	2.	Structured mitigation plans which include:					
	a)	Training of staffs	NA				
	b)	Policy and procedures	NA				
	c)	Evidence of delegation log	NA				
	d)	Documented data management strategies e.g: quality assurance and quality control	NA				
	e)	Reports	NA				
	f)	Acknowledgement by Head of Service and PIC/Hospital Director	NA				
	g)	Feedback given	NA				
26.5.1.3	Risk of chemical hazard, biological hazard, physical hazard of FCRC with laboratory facilities, these could relate to (if applicable)			NA			NA	
	EVIDENCE OF COMPLIANCE						
	1.	Documented policies and procedures for risk assessment plan	NA				
	2.	Mitigation plan for laboratory activities in FCRC which include:					
	a)	Training of staffs	NA				
	b)	Policy and procedures	NA				
	c)	Reports	NA				
	d)	Acknowledgement by Head of Service and PIC/Hospital Director	NA				
	e)	Feedback given	NA				
26.5.1.4	Risks of incident involving Investigational product (IP) or medical devices (MD) (if applicable): a) Discoloration b) Broken/malfunction c) Others			NA			NA	
	EVIDENCE OF COMPLIANCE						
	1.	Documented policies and procedures for risk assessment plan	NA				
	2.	Mitigation plan for risks IP or MD which include					
	a)	Training of staffs	NA				

	b)	Policy and procedure in place for transportation, storage dispensing, accountability and destruction of IP or MD	NA				
	c)	Reports	NA				
	d)	Acknowledgement by Head of Service and PIC/Hospital Director	NA				
	e)	Feedback given	NA				
26.5.1.5	The Head of the FCRC shall ensure that the staff are trained and complete incident reports which are promptly reported, investigated, discussed by the staff with learning objectives and forwarded to the Person In Charge (PIC) of the Facility. Incidents reported have had Root Cause Analysis done and action taken within the agreed timeframe to prevent recurrence.		NA			NA	
	EVIDENCE OF COMPLIANCE						
	1.	System for incident reporting is in place, which include:					
	a)	Training of staffs	NA				
	b)	Policy on incident reporting	NA				
	c)	Methodology of incident reporting	NA				
	d)	Register/records of incidents	NA				
	2.	Completed incident reports	NA				
	3.	Root Cause Analysis	NA				
	4.	Corrective and preventive action plans	NA				
	5.	Remedial measure	NA				
	6.	Minutes of meetings	NA				
	7.	Acknowledgment by Head of Service and PIC/Hospital Director	NA				
	8.	Feedback given to staff regarding incident reporting.	NA				
26.5.1.6	The FCRC shall oblige to any quality audit processes from either the Facility or relevant regulatory or certifying bodies.		NA			NA	
	EVIDENCE OF COMPLIANCE						
	1.	FCRC obliges to any quality audit processes from either the Facility or relevant regulatory or certifying bodies by providing audit reports and Corrective Action Preventive Action (CAPA) report.	NA				
26.5.1.7	There shall be participation from among FCRC staff in the monitoring and audit processes of the Facility.		NA			NA	

	EVIDENCE OF COMPLIANCE						
	1.	Evidence of participation among FCRC staff in the monitoring and audit process of the Facility.	NA				
26.5.1.8	The Head of FCRC ensures necessary actions shall be implemented to achieve planned results in line with the FCRC quality objectives.		NA			NA	
	EVIDENCE OF COMPLIANCE						
	1.	Relevant records on implementation of actions taken evidenced on-site.	NA				
26.5.1.9	Whenever relevant, the quality procedures shall be reviewed by the FCRC management in the interest of improvements to the Facility and FCRC quality systems.		NA			NA	
	EVIDENCE OF COMPLIANCE						
	1.	Adequate records on reviews and amendments by the FCRC management in the interest of improvements to the facility's and FCRC quality systems.	NA				
26.5.1.10 CORE	There is tracking and trending of specific performance indicators not limited to but at least two (2) of the following: a) number of training conducted per year (Target : minimum of 2 per year) b) number of publications per year (Target : minimum 2 per year)		NA			NA	
	EVIDENCE OF COMPLIANCE						
	1.	Written document for performance improvement activities	NA				
	2.	Assigned individual/committee for performance improvement activities	NA				
	3.	Records on safety and performance improvement activities.	NA				
	4.	Records on training conducted or part of organizing committee per year, e.g. Good Clinical Practise (GCP), Introduction to Clinical Research (ICR) and etc.	NA				
	5.	Records on Hospital/Facility Publication per year.	NA				
26.5.1.11	Feedback on results of safety and performance improvement activities are regularly communicated to the staff.		NA			NA	
	EVIDENCE OF COMPLIANCE						

	1.	Results on safety and performance improvement activities are accessible to staff.	NA				
	2.	Evidence of feedback via communication on results of performance improvement activities through continuing education activities/meetings.	NA				
	3.	Minutes of service/unit/committee meetings	NA				
26.5.1.12	Appropriate documentation of safety and performance improvement activities is kept and confidentiality of medical practitioners, staff and patients is preserved.			NA			NA	
	EVIDENCE OF COMPLIANCE							
	1.	Documentation on performance improvement activities and performance indicators.	NA				
	2.	Policy statement on anonymity on patients and providers involved in performance improvement activities.	NA				
26.5.1.13	FCRC shall follow the emergency/ disaster recovery plan by Facility. The disaster could be natural (e.g. floods, earthquakes, hurricanes, disease outbreaks), or manmade (e.g. urban fires, industrial accidents, bioterrorism). The disaster recovery plan may also be referred to as an emergency or contingency plan.			NA			NA	
	EVIDENCE OF COMPLIANCE							
	1.	Documentation on Emergency / Contigency Plan	NA				
	2.	Documented of FCRC staff responsibilities during emergency/disaster	NA				

TOPIC 26.6
SPECIAL REQUIREMENTS

STANDARD 26.6.1
Research (Industrial Sponsored Research, ISR) or Investigator Initiated Research (IIR)

CRITERION NO.	CRITERIA FOR COMPLIANCE			SELF RATING	FACILITY COMMENTS	SURVEYOR FINDINGS		
						AREAS FOR IMPROVEMENT / RECOMMENDATIONS	SURVEYOR RATING	RISK
26.6.1.1 CORE	There is a Facility Research Review Committee for reviewing minimal risk research protocol (IIR).			NA			NA	
	EVIDENCE OF COMPLIANCE							
	1.	Medical Research Ethics Committee/ Institutional Review Board / Independent Ethics Committee for research involve human subject.	NA					
	2.	Minutes of meetings of the above committee	NA					
	3.	Adequate documentation on protocol to review activities in hard copy/soft copy as required by Ethics Committee.	NA					
26.6.1.2 CORE	The research (Industrial Sponsored Research, ISR) or Investigator Initiated Research (IIR) shall obtain approval from relevant authority.			NA			NA	
	EVIDENCE OF COMPLIANCE							
	1.	Adequate documentation in hard copy/ soft copy on approval from relevant authority.	NA					

SERVICE SUMMARY	
-	
OVERALL RATING :	NA
OVERALL RISK :	-