2.4

Patient Rights and Education (PRE)

2.4 Patient Rights and Education (PRE)

The HCE shall define patient and family rights and responsibilities as per the guidelines provided by the PHC. The staff is aware of these and is trained to protect patients' rights. Patients are informed of their rights and educated about their responsibilities at the time of admission. They are informed about the disease, the possible outcomes and are involved in decision making. The costs are explained in a clear manner to the patient and/or family. Patients are educated about the mechanisms available for addressing grievances.

A Client/Patient Rights and Responsibilities Charter, as given in Annex A,is displayed in all client/patient areas.

STANDARD-11. PRE- 1: A DOCUMENTED PROCESS FOR OBTAINING PATIENT AND/OR FAMILY CONSENT EXISTS FOR INFORMED DECISION MAKING ABOUT THEIR CARE.

IND.72 General Consent For Treatment Is Obtained When The Patient Enters The Organization. Patient And/Or The Family Members Are Informed Of The Scope Of Such General Consent

Scope of General Consent

The client has the right to have correct information about his/her health status (unless explicitly requested not to do so), proposed treatment plan and all related issues in general. This information should be conveyed by the attending staff in a clear way and appropriate language. The client should have sufficient information to help him/her understand the issue and have informed decisions regarding treatment and management. A proposed format of General Consent Form is as given below:

Table 14: General Consent Form for Treatment

GENERAL CONSENT FOR TREATMENT

Patient Name: _____ S/O, D/O,W/O_____

Patient Birth Date: _____ NIC_____ Next of kin_____

Address: _____

1. **Treatment:** I request and authorize the provision of treatment and related Healthcare Services to me by _____Hospital/Physician/authorized designees. This may include routine diagnostics and medications.
2. **Rights and Responsibilities:** I have been informed by the Hospital about my Rights and Responsibilities i.e. what I am to expect from the hospital/staff and how I/my attendants are expected to conduct while in the hospital and in other aspects relevant to hospital/staff.
3. **Valuables:** I understand that _____ Hospital is not responsible for my/my attendants valuables or personal articles.
4. **Release of Information:** I understand that the confidentiality of all medical records will be protected to the full extent of the law. I authorize _____Hospital to release all information from my medical record, as applicable, to:
   1) Payers, organizations or insurance companies which are responsible, in whole or in part, for obtaining insurance benefits for me, for billing and/or paying my physician(s) bill, and for filing appeals of denial of benefits, so that the physician may be paid for the services provided to me;
   2) Independent auditors or review agencies retained by any third party payers and insurers to analyze the charges for services rendered to me.
   3) In order to improve service and provide valuable input, I also authorize _____ Hospital to release my demographic information to organizations retained by them for

customer satisfaction surveys.

5. **Payment:** I assign and authorize payment, for any treatment and all services rendered, directly to _____ Hospital from my insurance company or third party payer including, but not limited to commercial health insurance, automobile no-fault insurance and workers disability compensation insurance etc. In consideration of the professional services provided or to be provided to me, I agree to pay all charges not covered bymyinsurance company or any applicable health benefit including, but not limited to, deductibles, co-payments, non-coveredservices. I understand that it is my personal responsibility to pay _____ Hospital all charges for servicesrendered despite of any disputes or disagreements between my insurance company and myself.

I have read the consent form or it has been read to me and I am satisfied that I understand its contents. My questions have been answered to my satisfaction.

By signing this form, **I acknowledge that I have been offered and/or received the _____ Hospital Patients Charter and shall abide by it.**

_____

(Signature of Patient/Legal Guardian/Patient Advocate/Parent/Next of Kin-*Circle One*)

(Date) _____

IND.73 THE ORGANIZATION HAS LISTED THOSE SITUATIONS WHERE SPECIFIC INFORMED CONSENT IS REQUIRED

Scope of Informed Consent

Although the Client/Patient's general consent is obtained for the proposed care or treatment, a written consent is mandatory for any invasive procedures or operations.

The client's informed consent is a prerequisite to carry out any medical intervention and the patient has the right to refuse or to halt a medical intervention.

In different situations of healthcare provision or involvement of the client in any research activity, the mode of consent and action will be:

i. When a patient is unable to express his or her will and a medical intervention is urgently needed, the consent of the patient may be presumed, unless it is obvious from a previous declared 'Expression of Will' that consent would be refused in the situation.

ii. When the consent of a legal representative is required and the proposed intervention is urgently needed, that intervention may be made if it is not possible to obtain the representative's consent in time.

iii. When the consent of a legal representative is required, patients (whether minor or adult) must nevertheless be involved in the decision-making process to the fullest extent which their capacity allows.

iv. If a legal representative refuses to give consent and the physician or other provider is of the opinion that the intervention is in the interest of the patient, then in case of a non-emergency situation, the decision must be referred to a court or some form of arbitration.

v. In all other situations where the patient is unable to give informed consent and where there is no legal representative or representative designated by the patient for this purpose, appropriate measures should be taken to provide for a substitute decision making process, taking into account what is known and, to the greatest extent possible, what may be presumed about the wishes of the patient.

vi. The consent of the patient is required for the preservation and use of all substances of the human body. Consent may be presumed when the substances/body part are to be used in the current course of diagnosis, treatment and care of that patient.

vii. The informed consent of the patient is needed for participation in clinical teaching.

viii. The informed consent of the patient is a prerequisite for participation in scientific research. All protocols must be submitted to a proper ethical review committee. Such research should not be carried out on those who are unable to express their will, unless the consent of a legal representative has been obtained and the research would likely be in the interest of the patient.

As an exception to the requirement of involvement being in the interest of the patient, an incapacitated person may be involved in observational research which is not of direct benefit to his or her health provided that the person offers no objection, that the risk and for burden is minimal, that the research is of significant value and that no alternative methods and other research subjects are available.

IND.74 INFORMED CONSENT INCLUDES INFORMATION ON RISKS, BENEFITS, AND ALTERNATIVES AND AS TO WHO WILL PERFORM THE REQUISITE PROCEDURE IN A LANGUAGE THAT THEY CAN UNDERSTAND

Information about Risks, Benefits and Alternatives

It is the responsibility of the healthcare service provider that he/she should take the time to explain/discuss with the patient and his/her attendant about the:

i. Health status/clinical facts

ii. Diagnosis of the problem

iii. Proposed management plan

iv. Expected outcome

v. Costs (expected)

vi. Risks

vii. Preferences/choices of patients

viii. Follow up to the clients/patients

ix. Right to read own medical record/file

After giving information about diagnosis, management and follow-up, the HCP should check to ensure that client/patient has understood the advice. Obtaining this feedback is vital in assessing to what extent the instructions have been understood.

Treating clients/patients with respect, actively listening to them, asking questions about their choices/preferences, praising, explaining diagnosis and management, describing the follow-up plan, and taking feedback about their understanding of the given advice/choice are all very important components of healthcare delivery.

The person performing the procedure shall be responsible for the entire consent process including providing explanation and taking the signature. A team member can take consent on behalf of the person performing the procedure, but their name and designation must be clearly mentioned in the chart.

When the patient does not speak or understand the predominant language of the community, the hospital will make efforts to ensure that proper interpretation is done if it is possible to provide an appropriate interpreter for the same.

The informed consent process adheres to statutory norms including:

a. Taking consent before the procedure.

b. At least one independent witness signing the form.

c. Taking consent every time (especially for procedures which the patient has to undergo their whole lives). However the repeat consent could be verbal for the same procedure e.g. dialysis.

d. Taking a fresh consent (for the new procedure) in case the procedure has to be changed during course of treatment/procedure.

e. Appropriate information is provided to clients/patients and their families, in a way that they can understand, on the proposed treatment, the costs, the risks and benefits of the proposed treatment or investigation, and the alternatives available.

f. Clients/Patients and their families are fully informed about the client's/patient's health status, including the clinical facts about their condition, unless there is an explicit request not to disclose a particular information to the patient/relatives.

Table 15: Sample Consent Form

Patient's Informed Consent to Treatment or Investigation {To be filled by Treating Consultant} (Page1 of 2)	Name of HCE:	Patient's Reg. #:
	Patient's name:	
	CNIC#:	
	S/O, D/O, W/O:	
	Age:	**Sex:**
	Address:	
	Diagnosis:	

Declaration of Doctor/Proceduralist (to be completed by the clinician obtaining consent)

Tick the boxes or cross out and initial any changes or information not appropriate to the stated procedure

- ○ I have informed the patient of the treatment options available, and the likely outcomes of each treatment option, including known benefits and possible complications. (State options)

1.
2.
3.
4.

- ○ I have recommended the treatment/procedures/investigations noted below on this form.
- ○ I have explained the treatment/procedures/investigations, identified below, and what i entailed for the patient.
- ○ I have provided the patient with information specific to the procedure identified. Th

patient has been asked to read information provided and ask the doctor/proceduralist questions about anything that is unclear.

- I have provided to the patient an identifiable copy of the information which has been kept on the patient's medical record.
- Information provided to the patient includes:

Open access procedures

I have given the patient opportunity to discuss the proposed procedure, benefits and risks, both general and specific, and the risk of not having the procedure.

Other procedures

I have discussed the alternative procedures, benefits and risks, both general and specific, and the risks of not having the procedure.

Treatment/procedure/investigation

List the treatment/procedures/investigations to be performed, noting correct side/correct site

This procedure requires: □ General and/or Regional Anaesthesia□ Local Anaesthesia

□ Sedation

An anaesthetist will explain the risk of general or regional anaesthesia to the Patient at least 12 hours prior to the treatment.

Disclosure of material risks

Material risks or specific risks particular to this patient that have arisen as a result of our discussions are:

Signature of doctor/proceduralist obtaining consent

Full name (please print) _____

Position/Title_____

Signature _____

Date_____

Signature of doctor/proceduralist with overall responsibility for treatment (if different)

Full name (please print) _____

Position/Title_____

Signature _____

Date_____

Please Note: ***A separate consent form (signed by the patient/relative) for blood transfusion as per relevant protocols is mandatory.***

Patient Consent to Treatment or Investigation (Page 2 of 2)	**Name of HCE:**	Patient Reg. #:
	Patient's name:	
	CNIC#:	
	S/O, D/O, W/O:	
	Age:	**Sex:**
	Address:	
	Diagnosis:	

Patient's declaration

Please read the information carefully and tick the following to indicate you have understood and agreed with the information provided to you. Any specific concerns should be discussed with your doctor or proceduralist performing the procedure ***prior to signing the consent form.***

i. The doctor/proceduralist has explained my medical condition and prognosis to me. The doctor/proceduralist also explained the relevant diagnostic, treatment options that are available to me and associated risks, including the risks of ***not*** having the procedure.

ii. The risks of the procedure have been explained to me, including the risks that are specific to me and the likely outcomes. I have had an opportunity to discuss and clarify any concerns with the doctor or proceduralist.

iii. I **understand** that the result/outcome of the treatment/procedure cannot be guaranteed.

iv. I **understand** that if I am treated as a public patient, no guarantee can be provided that a particular doctor/proceduralist will perform the procedure, and that the

doctor/proceduralist performing the procedure may be undergoing Post Graduate training under supervision of the consultant. (The hospital should define that a PG trainee is authorized to perform a procedure in which year and whether supervised or unsupervised).

v. I **understand** that tissue samples and blood removed as part of the procedure or treatment will be used for diagnosis and common pathology practices (which may include audit, training, test development and research), and will be stored or disposed of sensitively by the hospital.

vi. I **understand** that a photograph, if taken during examination/procedure or treatment, will be used for academic purposes only and that too ensuring confidentiality and privacy.

vii. If a staff member is exposed to my blood, I **consent t**o a sample of blood being collected and tested for infectious diseases. I understand that I will be informed if the sample is tested, and that I will be given the results of the tests.

viii. I **agree** for my medical record to be accessed by staff involved in my clinical care and for it to be used for approved quality assurance activities, including clinical audit.

ix. I **understand** that if immediate life-threatening events happen during the procedure, I will be treated accordingly.

x. I **understand** that I have the right to change my mind at any time before the procedure is undertaken, including after I have signed this form. I understand that I must inform my doctor if this occurs.

xi. I **consent** to undergo the procedure/s or treatment/s as documented on this form.

xii. I **consent** to a blood transfusion, if needed ☐Yes ☐ No

Please Note: ***A separate consent form for blood transfusion as per relevant protocols is also to be signed.***

Patient's full name_____

Patient's signature _____

Date/Time_____

Parent/guardian signature _____

Date/Time_____

(if desired for mature minor)

Interpreter's declaration

Specific language requirements (if any)_____

Interpreter services required: ☐Yes ☐ No

I declare that I have interpreted the dialogue between the patient and health practitioner to the best of my ability, and have advised the health practitioner of any concerns about my performance.

Interpreter's signature _____

Date_____

Full name (please print)_____

Confirmation of consent at pre-admission or admission to hospital

I confirm that the request and consent for the operation/procedure/treatment above remains current.

Patient's signature _____

Date/Time_____

(Patient/Person responsible)

IND.75 THE POLICY DESCRIBES WHO CAN GIVE CONSENT WHEN PATIENT IS INCAPABLE OF INDEPENDENT DECISION-MAKING

Policy Regarding Consent for Incapacitated Patient

The HCE shall take into consideration the statutory norms. This would include taking of consent from next of kin/legal guardian. The order of preference is; spouse, son, daughter, brother, sister, parents. However, in case of unconscious/unaccompanied patients the treating doctor can take a decision in life-saving circumstances.

STANDARD-12. PRE-2: PATIENT AND FAMILIES HAVE A RIGHT TO INFORMATION ON EXPECTED COSTS

IND.76 THERE IS UNIFORM PRICING POLICY IN A GIVEN SETTING (OUT-PATIENT AND WARD CATEGORY

Tariff Policy

There should be a Tariff/Billing policy which defines the charges to be levied for various activities/procedures. The policy shall be clearly activity/procedure based.

IND.77 THE TARIFF LIST IS AVAILABLE TO PATIENTS

Tariff List

The HCE shall ensure that there is an updated tariff list and that this is available to patients when required. The HCE shall charge as per the tariff list without any hidden costs whatsoever. Any additional charge should also be enumerated in the tariff and the same communicated to the patients with a clear and justified explanation. Tariff rates should be uniform and transparent.

The Reception Area/Almoner Department/Account Section and wards display information about the tariff policy of the HCE which shall include:

i. The rights of the clients/patients.
ii. Services and facilities available in the hospital.
iii. Costs of services.
iv. Feedback and complaints pathways.

IND.78 PATIENTS AND FAMILY ARE EDUCATED ABOUT THE ESTIMATED COSTS OF TREATMENT

Information about Estimated Cost of Treatment

The patient and/or family members are explained about the expected costs.

Patients should be given an estimate of the expenses on account of the treatment/investigations to be performed in different settings, preferably in a written form. This estimate shall be prepared on the basis of the treatment/management plan. For example, a family attending the hospital for antenatal care must be informed about the cost of prospective C-Section, in case the SVD does not take place. Similarly a patient requiring long

term care such as cases of chronic illnesses/cancerous diseases should also be informed of the likely expenses.

It could be prepared by the OPD/Registration/Admission staff in consultation with the treating doctor.

IND.79 PATIENTS AND FAMILY ARE INFORMED ABOUT THE FINANCIAL IMPLICATIONS WHEN THERE IS A CHANGE IN THE PATIENT CONDITION OR TREATMENT SETTING

Information about Financial Implications

When patients are shifted from one setting to another, typically to and from ICUs, other specialized care facilities, the financial implications must be clearly conveyed to them.

STANDARD-13. PRE-3: PATIENT RIGHTS FOR APPEALS AND COMPLAINTS

IND.80 THE ORGANIZATION INFORMS THE PATIENT OF HIS/HER RIGHT TO EXPRESS HIS/HER CONCERN OR COMPLAIN EITHER VERBALLY OR IN WRITING

Right to Express Concern or Complain

An institutionalized, accessible and transparent grievance redress mechanism must be in place. The information as how to lodge a complaint must be clearly displayed in the local language at prominent places.

Complaint is an expression of client dissatisfaction and a way of feedback on the quality of care which needs a response. Every healthcare facility should inform the clients/patients about their right to complain and the complaint handling procedures. A complaint may be written or verbal and be lodged by the patient, his/her attendants or a legally authorized person. Various ways should be adopted, for example:

a. Display the message clearly in the local language at prominent places in the facility such as registration desk, waiting area, OPDs, main entrance and private rooms etc.
b. Pertinent information may be made available in the form of leaflets/brochures at appropriate places.
c. Client feedback/satisfaction must be sought on a prescribed but simple format at the time of discharge. (Format attached as **Annex B**).

IND.81 THERE IS A DOCUMENTED PROCESS FOR COLLECTING, PRIORITIZING, REPORTING AND INVESTIGATING COMPLAINTS, WHICH IS FAIR AND TIMELY

Complaint Management Procedure

To become a quality driven service, a facility should encourage the clients and their family members to freely raise and discuss their views, concerns or complaints with the concerned staff. These dialogues help and serve as opportunities for improvement.

Every HCE must have a documented grievance redressal procedure, entailing collecting, prioritizing, investigating, resolving and reporting complaints. A proposed format for the Complaint Management Procedure is attached as **Annex C**

The complaints against service providers that carry client's perspective should be handled first by the manager/concerned HoD/unit. For example the OPD in-charge should tackle the

complaints, verbal or written, related to the OPD and should take remedial action there and then. In case actions are beyond his/her mandate he/she, must refer it to the Complaint Cell.

A Complaint Cell should be established at every hospital and resourced properly. The Complaint Cell shall essentially comprise of a core staff and be headed by a manager appointed by the HCE and be supported by a team of experts (Complaint Management Committee- CMC). The department/specialist against whom a complaint is received/under investigation will not be part of the committee for that particular case. The CMC may co-opt an expert for assistance. Every complaint must be thoroughly investigated and documented. The Complaint Cell will maintain department wise records of complaints investigated and actions taken. A record of the Complaint Register must lie in the office of the MS or In-charge of the health facility, with the complete number and details of complaints received and action taken.

The detailed policy of the HCE for documentation of the processes should define credible and transparent mechanisms for receiving and handling complaints against the functioning of the HCE and practice of its staff. This mechanism should be used fairly and timely for collecting, prioritizing, reporting and investigating complaints. To ensure that measures for patient complaint system are effective and efficient, they should be well-targeted and focused to address the identified problems.

IND.82 THE ORGANIZATION INFORMS THE PATIENT OF THE PROGRESS OF THE INVESTIGATION AT REGULAR INTERVALS AND INFORM ABOUT THE OUTCOME

Information about Progress of Investigation and Outcome

It is important that the client/patient is informed of the level at which the complaint can be handled. This duty should be clearly entrusted to a designated staff member of the complaint cell/department of the HCE. The client should be kept informed about the progress of the investigation at regular intervals, in case these are prolonged, and also of the outcome. This will help to build the credibility of the process/facility.

IND.83 THE ORGANIZATION USES THE RESULTS OF COMPLAINTS INVESTIGATIONS AS PART OF THE QUALITY IMPROVEMENT PROCESS

Feedback and Quality Improvement

Transparency of decisions must be ensured and the verdicts of inquiries should not be biased in favour of the facility staff. If professional misconduct or negligence is involved then it should be forwarded to the professional regulatory body at the appropriate level, by the in charge of the HCE. Most importantly the result of the inquiry should be taken in a positive manner and an

executive committee of the HCE should ensure that the remedial measures suggested by the CMC as an outcome of the inquiry should be implemented/enforced for the improvement of the system forthwith.

Feedback from clients includes both compliments (satisfaction) and complaints (dissatisfaction) about quality of care. Client/patients feedback should be valued, as this would help the HCE to improve quality of services.

The hospital should have mechanisms to obtain feedback as an on-going process. The feedback mechanisms should be culturally appropriate and feasible and may include:

i. A suggestion/complaint box at the facility that may be used by the literate clients.

ii. Periodic clients exit interviews.

iii. Key informant interviews on periodic basis (within community).

iv. Mystery client survey.

v. Focus group discussions.

HCEs should devise a method and frequency of feedback mechanisms to seek the experiences of clients about the quality of care. The HCE management should decide on a method for itself, depending upon its needs and resources. However a hospital should allocate sufficient resources, as these will be required to hire people for conducting and analyzing such exercises.