

POLICY TITLE	National Informed Consent Policy
POLICY OWNER	Accreditation & Quality Group
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1. PURPOSE:

The purpose of this policy is to establish the process for obtaining general and specific informed consent for health care procedures, anesthesia, and other activities in patient care.

2. SCOPE:

Consent applies to all investigational and therapeutic interventions outlined in this policy.

3. DEFINITIONS & ABBREVIATIONS:

Definitions:

Adult: A person/patient who has reached the legal age of 18 years.

Minor: Any person who is below the age of 18 years of age.

Guardian: A person who is authorized to consent on behalf of the patient based on the laws of the Kingdom of Bahrain.

- **Exception:** Cosmetic surgeries, Interventional cosmetic procedures, and for involvement in research studies, the age should be 21 or above.

Substitute Consent Giver: A person may act as the consent giver if the patient is unable to do so. This person is usually a close relative and should have familiarity with the patient's presumed wishes regarding medical care.

Advance Health Care Directive: A document that describes a clinical situation and clearly states the patient's understanding and wishes regarding that situation. To be valid, an advanced health care directive must be signed and dated by the patient and a witness.

Physician: All doctors, including physicians and dentists.

Attending Physician: A physician who is responsible for the overall care of a patient.

Junior Medical Staff: Any physician employed by the HCF primarily in a service capacity, who is supervised and responsible to a member of the consultant Medical Staff. This includes residents, senior residents, and chief residents.

Trainee: Any physician or student in a health care discipline who is performing a training rotation in the HCF. This includes, but is not restricted to, Medical Students, Interns, Residents, Senior Residents, Chief Residents, and Fellows. These trainees are supervised by and responsible to a member of the Consultant Medical Staff.

Consent: A declaration of the patient or their guardian of willingness to undergo a procedure, investigational or therapeutic, or other intervention.

Informed consent: The patient's or their guardian's agreement for the performance of a procedure and/or treatment, based on essential information being disclosed to them including the nature of the intervention, alternative options of interventions available, the inherent risks and benefits of the intervention, the consequences of non-treatment, any expected result or outcome of treatment and the name of the physician(s).

Implied Consent: Is the implicit agreement of the patient to undergo certain non-invasive medical procedures, such as vitals monitoring, medical examination, and radiological or laboratory testing.

Explicit Consent: It is the patient's clear and explicit declaration of their willingness to undergo specific medical examinations, treatments, or surgeries.

General Consent to Treat: A consent that gives the HCF permission from the patient or an appropriate legal/cultural representative to perform normal medical interventions, such as the administration of medications, assessments, and examinations, and appropriate noninvasive procedures considered routine in the provision of patient care.

Incompetent patient: A person may be judged incompetent if, for any reason, it is felt that he/she is unable to understand the information provided during the consent process. Reasons for declaring incompetence may include, but are not limited to, the following conditions: inadequate age, mental disability, impairment of judgment by drugs or medications, and acute disturbances of consciousness, reasoning, or memory caused by disease.

Non-invasive procedure: A diagnostic effort or treatment that does not invade the bodily integrity of the patient or does not require entering the body or puncturing the skin.

Invasive Procedures: Any procedure that invades the patient's bodily integrity and involves puncture or incision of the skin, the insertion of an instrument, the injection of foreign material into the body, a reaction due to the administration of a drug or fluid, or that places the patient at risk.

Emergent Condition: Is the occurrence of a medical condition of sufficient magnitude that there is an impending risk to life, limb, or function that is so grave that instantaneous intervention is required to attempt to prevent mortality or significant morbidity.

Coercion: To compel someone to act against their will by intimidation or threats.

Abbreviations:

- **NHRA** – National Health Regulatory Authority
- **HCF** – Health Care Facility

4. POLICY STATEMENT:

The National Health Regulatory Authority (NHRA) supports patients' right to participate in informed decision-making, which requires the disclosure of adequate and accurate information relevant to medical procedures.

NHRA mandates that all Health Care Facilities (HCF) must provide patients, those they authorize to make decisions on their behalf, or their Substitute Consent Givers, with information that will enable them to fully participate in medical treatment decisions.

All HCF must respect social traditions and local customs regarding consent.

5. PROCEDURES:

Responsibility:

It is the responsibility of the attending physician and/or his or her physician designee to obtain appropriate written informed consent before any diagnostic or therapeutic invasive procedure is performed.

The admissions staff in HCF will normally obtain General Consent to Treat.

Reception staff in primary care, polyclinics, and the Emergency Department will be responsible for obtaining General Consent for Treatment.

Procedures:

A "Consent for Surgery or Special Procedure" form must be used if the proposed intervention involves any invasive diagnostic or therapeutic procedure with material or specific risks. Material or specific risks exist when the information provided would cause a reasonable person to have to decide whether to proceed or not with a particular procedure.

Implied Consent:

The general presentation of oneself for treatment or diagnosis in the Emergency Department, Clinics, Laboratory, Radiology, or allied services would be construed as implied consent to treatment.

Explicit Consent:

Explicit consent may be verbal or written.

Verbal consent:

This type of consent is usually obtained from a patient before an examination or before the patient agrees to a treatment plan.

Written consent:

This type of consent is reserved for any diagnostic or therapeutic intervention that involves the patient's bodily integrity. It is the responsibility of HCF to provide the appropriate forms for this purpose. In the case of a "minor", consent should be obtained from the "Substitute Consent Giver" or Guardian. Written consent may be obtained in handwritten or electronically/digitally signed format, executed by the patient while physically present at the facility. Electronic or digital signatures are legally approved and accepted for consent documentation.

ELEMENTS OF A VALID CONSENT:

Consent is valid only when the eight critical elements are present. The eight critical elements are:

1. Competency (decision-making ability):

This refers to the patient's ability to understand the nature and consequences of a treatment decision.

It is assumed that all patients are competent to give an authorization for treatment in the absence of evidence to the contrary. Health care providers are to assume the patient's competency, except where there is contrary evidence, and thus respect the patient's right to decide what is or is not to be done to his or her body.

The competency of any patient, when doubted, is determined by whether the patient is capable of understanding the nature and consequences of a treatment decision, not by the rejection of the treatment.

2. Capacity to make treatment decisions:

The capacity to make treatment decisions refers to the intellectual ability to reach a reasoned choice about treatment.

It verifies that such things as mental illness, emotional disturbance, medical conditions or chemical dependence do not impair the person's overall competency. It is assumed that all patients are capable of authorizing treatment. The health care provider who doubts a patient's capacity to make a treatment decision is responsible for assessing the patient's situation and documenting their professional judgment, or for requesting the advice of a more senior person or a person from a different specialty.

3. Disclosure of information:

Certain information must be disclosed to patients or their guardians before they give informed consent to treatment. The disclosure of information may be verbal or written. Other methods of disclosure may be used, such as videotapes or CDs. This information includes:

3.1. Diagnosis and nature of illness:

The physician is required to inform the patient or their guardian of the diagnosis reached and the natural course of the patient's illness.

3.2. Nature and Purpose of Proposed Intervention:

The health care provider informs the consent giver of the nature of the proposed intervention, its justification, and its intended purpose.

3.2. Probable Risks and Benefits of the Proposed Intervention:

This requires disclosure of all risks that are likely to affect the patient's consent. It does not require disclosure of all known risks. However, risks with low probability and grave consequences, as well as risks with high probability and minor or grave consequences, are to be disclosed.

3.3. Reasonable Alternatives:

If treatment alternatives exist, they are to be disclosed to the patient or their guardian. What is reasonable will depend on the balance of risks and benefits of the alternative interventions. The expected immediate and long-term impacts of treatment on the patient's lifestyle should be explained. It is the responsibility of the health care provider to explain the issue of lifestyle with a view to, and with information deemed material to, the patient's choice.

3.4. Consequences of Refusing, Diagnostic Tests, or Treatment:

As an extension of the principles of informed consent and as part of the consent process, the patient and their guardian must be informed of the nature and consequences of refusing to undergo the proposed medical intervention.

The health care provider must avoid unduly influencing or coercing patients into treatment. It is the responsibility of the health care provider to ensure that the potential problems arising from refusal of treatment are fully understood by the patient.

3.5. Who is to perform the procedure:

The health care provider should inform the patient that performing the procedure may involve a number of qualified healthcare professionals. Where the facility is a teaching hospital where interns, residents, senior residents, or other health care professionals may participate in interventions under the supervision of the attending physician.

3.6. Change or extension from the specific treatment:

When the health care provider has material information about the probability and/or possibility of change or extension from the specific treatment for which consent is being requested, such information must be disclosed to the consent giver.

4. Understanding:

The health care provider must assess the patient's or their guardian's level of understanding of the information presented regarding the proposed intervention. If the patient or their guardian does not understand the information presented to them or they have misconceptions about certain aspects of the intervention, for example, an overestimated rate of success or dismissal of grave risks, more effort should be placed on correcting the patient's level of understanding prior to obtaining the consent of the patient and the initiation of the intervention.

5. Specificity

The consent authorization must be specific for the intervention to be performed. A physician/health care provider has no right to exceed the scope of the consent and engage in other interventions, except those deemed necessary in the course of treatment by the attending physician. The consent must include the specific procedure, sub-procedure, and variations of the procedure.

6. Opportunity for questions and answers:

The consent process depends on effective communication. Opportunity must be given to have questions answered in an understandable fashion, to allow time for integration of the information, and to consult with others before the decision is made. All reasonable steps must be taken to maintain good communication and avoid rushing the consent process. Clear and accurate information must be provided in a language and vocabulary understandable to the consent giver. Communication difficulties may be overcome through the use of competent translators and/or appropriate technologies.

7. Voluntariness

Consent must be free of undue influence and coercion. The physician's discretion allows for the presentation of accurate information with minimal influence. The goal for physicians should be to present pertinent information in a way that allows the consent giver to make an independent, reasoned choice about care.

8. Accuracy

The consent obtained must be free of misrepresentation of material information.

The physician must always give accurate information about proposed treatments. Intentional withholding of information, coercion, and undue influence invalidate authorization. Misrepresentation can be in the form of well-intentioned exaggeration, distortion, or trivialization of essential information.

Wittiness Consent:

The witness for the consent must be someone other than the primary operator for the intervention. The signing witness

must observe the discussion of the procedure and the signing of the forms. When a translator is required, the translator should function as a witness.

Duration and Validity of the Consent:

A valid consent endures (30 days) from the time the consent is given to the time the intervention and/or treatment commences, unless:

- a. It is withdrawn by the consent giver; or
- b. A change is made in the planned and consented to intervention; or
- c. An assessment indicates the patient's condition has changed.

If the consent is invalidated by one of the above, the consent must be renewed and verified by the attending physician's signature and date, and the consent giver's signature and date.

The attending physician is responsible for ensuring that the consent remains valid from the time of consent to the commencement of the intervention.

Duration Exception:

1. Blood Components consents:

Once obtained, the patient's consent to receive blood components remains valid throughout the patient's hospital stay. However, the patient or the substitute consent giver must be informed of each required transfusion.

At any time prior to a transfusion, the patient has the right to revoke consent.

2. Duration Exception for Dialysis:

Consents for dialysis remain valid, unless revoked by the patient, throughout the course of the same treatments.

Consent Giver:

An adult, male or female, is presumed to be capable of giving consent unless there is evidence to verify incompetence regarding the decision to be made. Such evidence must demonstrate that at the time of consent, one of the critical elements of valid consent was absent.

Exceptions:

In accordance with local law and cultural tradition, only the procedures involving reproductive interventions for male and female patients require informed consent of the patient as well as the husband/wife or legal guardian, regardless of age.

Substitute Consent Giver for Incompetent Adults:

Ideally, all patients must consent to the treatments and procedures performed on them. However, in some cases, the patient may be unable to understand the risks and benefits of the proposed treatments. Consent obtained under those circumstances would not be valid, as it is obtained from an incompetent patient.

To help ensure that any treatment or procedure that would normally require consent is not performed inappropriately, a substitute consent giver must be asked to consent on the incompetent patient's behalf. In such cases, both the patient (if able) and the substitute consent giver should sign the consent form.

The following is an order of preference for selecting a substitute consent giver:

1. A decision-maker duly appointed by the patient at such a time that he/she was competent. Ideally, this appointment will be in writing and witnessed.
2. A guardian appointed by a court of Law.
3. An adult relative who has had substantial personal involvement with the patient in the preceding 12 months. The priority sequence is: Father, Mother, Brother, Sister, Uncle (from father's side, then from mother's side), Grandfather, Grandmother, Other relatives from father's side, then other relatives from mother's side. If the patient is a married female, the Husband is prior to the father.
4. The incompetent patient's health care professional is responsible for the overall care of the patient and not responsible for the particular procedure in question.

When a given substitute consent giver is unavailable, unwilling, or unable to participate in the consent-giving process, responsibility passes to the next available person on the list.

If, however, consent is refused, such a consent giver will be the final authority for the purposes of this policy.

If there is any question about a patient's competence, consultation should be sought from a specialist in neuroscience, specifically a neurologist or psychiatrist, as appropriate. In obvious situations, the judgment of a duly licensed medical doctor will suffice.

Substitute Consent Givers for Minors:

Substitute consent givers for minors are expected to act in the best interests of the minor. The substitute consent giver must have assumed guardianship of the minor.

1. The father:

The father consents to a child as a minor who lacks the capacity to consent for themselves. (Father can consent for his children even if the father is less than 18 Years of age).

2. Divorced Parents:

The parent who has custody is the appropriate person to give consent.

The other parent has the right to information regarding the child's medical condition and/ or treatment.

3. The mother:

The mother can consent for a child in an emergency or urgent situation when the father is not present. (Mother can consent for her children even if she is less than 18 Years of age). After the mother, the priority is in the following sequence: Brother, Sister, Uncle (father's side first, then mother's), Grandfather, Grandmother, Other relatives from father's side, then other relatives from mother's side.

4. Legal Guardian:

A legal guardian may give consent on behalf of the minor. Typically, this would be a case in which the child lives with grandparents or other family members who have legal guardianship status from an authorized Court of Law.

5. Minors in Government Homes:

The Court or its delegate is the proper person to give consent if the child is a permanent resident of a governmental home.

6. Temporary childcare responsibility:

Temporary childcare workers, such as day care personnel and babysitters, must have authorization from the appropriate guardian before they can consent.

Written authorization must identify the child, the temporary guardian, the specific times and dates during which the delegation is authorized, and any restrictions on the delegation. The authorization must be signed and dated by the proper guardian and a witness. In a non-emergency case where the guardian cannot be contacted, treatment is initiated in the patient's best interests and continues until the consent giver is available. In such a case, it is good practice to inform the patient's relative at the hospital.

7. Incompetent parent (or guardian):

A parent or guardian is incompetent if he or she cannot grasp the generalities of:

- a. The information and opinion given.
- b. The condition is being treated.
- c. What does it mean to refuse treatment?
- d. And the proposed treatment.

In this case, an alternate consent giver should be chosen.

Authorization by Guardian for Temporary Caregivers:

Except in an emergency, a father/guardian with lawful custody must, in writing, authorize a temporary caregiver to consent to the treatment of a minor child.

Requirements:

A copy of the document authorizing a temporary caregiver to consent to treatment of a minor must be filed in the

patient's health record.

If a temporary caregiver presents with a minor child requiring non-emergency treatment and lacks written authorization from the father/guardian, telephone consent must be obtained.

Consent for Temporary Absence from the HCF:

Consent must be obtained from either the father or from the substitute consent giver for a minor or an incompetent adult who is an inpatient of the HCF to:

- a. Be transported to, or participate in, activities outside the HCF.
- b. Visit with, and be transported by, people other than the parent or substitute consent giver during the day or overnight. When providing consent, the father/substitute consent giver must supply the names, addresses, relationships, and telephone numbers of such people.

Consent for Discharge of a Minor Unescorted by a Guardian:

Consent must be obtained from the father/ guardian for the discharge of a minor unescorted by a parent/ guardian.

Requirements:

If it is known that a minor may be discharged without a parent/guardian in attendance, or to a person other than a parent/guardian, consent should be obtained prior to discharge.

If it is not known until discharge, telephone consent must be obtained.

The father/ guardian must provide the name and relationship of the person responsible for escorting the minor home.

Consent for Surgical and/or Invasive Procedures:

The physician who is to perform a procedure for which consent is considered necessary is responsible for obtaining consent.

The physician to perform the procedure is ultimately responsible for ensuring that all relevant information is provided to the consent giver in a setting conducive to an independent and reasonable decision.

Delegation of the duty to disclose information for purposes of consent may only be given to another physician capable of answering questions regarding the procedure and the implications of the procedure to the patient. This presumes that the physician providing the information is familiar with the patient's medical history.

Responsibility for procuring valid informed consent remains with the attending physician.

Procedures:

- a. The physician, or their physician designee, is responsible for assuring that the consent is 'informed' and appropriately signed.
- b. The physician informs the patient of the intervention, risks and benefits, any alternative treatment, and the risk

of not accepting recommended treatment, and acquires and documents the consent.

- c. The patient or authorized person has the right to an explanation of the consent form, the opportunity to read the form (or have it verbally explained in a language he can comprehend), and to have any relevant questions answered. The patient should be assessed as being oriented to person, place, and time and not receiving any mind-altering medications.
- d. The patient has the right to put a line through (or mark) a section or phrase of the consent form which indicates patient/guardian exceptions to consent. In such cases, each alteration made should be countersigned by the consent giver.
- e. A consent form is required for specific interventions as a record of the patient's understanding and agreement.
- f. The completed form becomes part of the patient's permanent health record.
- g. For elective procedures, consent should be obtained in a suitable environment with adequate time to discuss details of the procedure.
- h. In urgent situations where ideal circumstances may not exist, every effort should be made to ensure valid consent.
- i. In life-threatening situations, obtaining valid consent is not necessary.
- j. If the patient has been pre-medicated (analgesics, sedatives, or other drugs that may alter his or her ability to understand or make decisions), he or she must be assessed regarding his or her capacity to make a rational decision and to give valid consent. Documentation of these circumstances must be entered into the patient's health record by the physician obtaining consent.

Exceptions:

- a. In accordance with cultural tradition: Only the procedures involving productivity in male and female patients require informed consent of both the patient and the husband, wife, or legal guardian, regardless of age.
- b. Consent does not need to be re-signed unless the clinical situation has changed.
- c. Consents for minors must be signed by the appropriate guardian.
- d. Any alteration to a completed consent form must be made before the intervention commences, and the alteration must be signed and dated by the consent giver and the attending physician.
- e. Notation of the alteration and the reason for it must be entered in the patient's health record by the attending physician.
- f. The consent form should list the names of the physician/surgeon, or physician/surgical group, who may participate in the procedure.
- g. The names of the procedure must be written on the consent form. If such information is not written, the physician or surgeon must be contacted to provide accurate information.
- h. Surgical and/or invasive procedures should be legibly printed and must state the exact location (for example, right or left side).

- i. If the patient has questions regarding the procedure, the outcome, or alternatives, notify the physician or surgeon before proceeding.
- j. Questions regarding preparation, nursing care, etc., may be answered by the nurse.
- k. The patient must be asked to sign his or legal name and identity number on the consent form in the appropriate section. If the patient is unable to sign, have the legal/cultural representative sign with the legal name and identity number and indicate their relationship to the patient. The physician or nurse must witness the signature.

Obtaining Consent for Anesthesia:

Separate consent forms must be established for anesthesia. It is the responsibility of the anesthesiologist performing the procedure or his appropriate designee to obtain appropriate informed consent prior to the administration of anesthesia. Information provided through programs such as patient teaching, videos, and literature helps to educate the patients and complements the information provided by the physician. It is not, however, intended to replace the information exchange between the physician and the consent giver.

Delegation and Sub-delegation:

The authority given by attending physicians to delegate to another physician must extend only to the one named as a delegate. Such delegation must be documented in a clinical record.

A delegated physician cannot further delegate (sub-delegate) activity to a third physician without having specific direction and authority from the consent giver and attending physician.

The authorizing physician must be satisfied that the delegated physician is competent and qualified to perform the procedure or treatment.

The attending physician remains ultimately responsible even after delegation.

It is not considered a delegation of a procedure or treatment when the physician named on the consent form to undertake a procedure does so in cooperation with or with the assistance of other physicians, be they members of the junior medical staff, medical trainees, or consultants.

Supervision of Junior Staff and Medical Trainees:

Members of the junior medical staff or medical trainees may participate in the care and treatment of patients under the supervision of the authorized physician.

Patients and consent givers must be informed that the facility is a teaching facility and, therefore, members of the junior medical staff or medical trainees may participate in their care.

The authorized physician must be satisfied that the assisting physician is competent and qualified to perform the procedure or treatment.

Refusal of Consent:

A patient must be fully informed about the various treatments and procedures that are necessary according to the attending physician(s) and understand the risks and benefits of the proposed treatments.

Once fully informed, a competent adult has the right to choose among different treatment alternatives or to refuse all forms of treatment, even though such refusal may endanger life or health.

Where intervention is refused or when a patient self-discharges, the physician has an obligation to make reasonable attempts to inform the patient of the risks involved in refusal, including grave risks.

The physician must document in the patient's health record that the information was provided. Ideally, when treatment is refused, the patient should sign a Refusal of Treatment form.

Refusal of Consent for a Minor or an Incompetent Adult by a Guardian:

The substitute consent giver for a patient must be fully informed about the various treatments and procedures that are necessary according to the attending physician(s) and understand the risks and benefits of the proposed treatments.

A substitute consent giver has the right to refuse an intervention for a minor or an incompetent adult who is incapable of giving valid consent except in life-threatening conditions.

When treatment is refused, the substitute consent giver must sign the Refusal of Treatment form.

Exceptions to Refusal:

- a. If reckless refusal of medical care by the Substitute Consent Giver may endanger the patient's life, it may be appropriate for the hospital to obtain the consent of two consultants within the institution in order to perform the intervention.
- b. If one relative gives consent for the intervention while another refuses, it is acceptable to proceed based on the consent provided and to also obtain agreement from two consultants
- c. The individual patient has, as a competent adult, prepared an advanced health care directive specific to the intervention.

Obtaining General Consent to Treat:

The hospital's admissions department is responsible for obtaining general consent for treatment. The patient and/or legal representative must be given General Consent on presentation to the appropriate admissions area.

The consent is provided in Arabic and English, and an interpreter is available if needed.

The patient must be asked to sign their legal name and identity number in the appropriate section of the form. If the patient is unable to sign, have the authorized person sign on the patient's behalf. The legal representative must sign and indicate their relationship to the patient.

A Thumbprint can also be used instead of a signature if the patient is unable to write.

If the patient or guardian refuses or is unable to consent, the bottom of the consent form should be completed, documenting the refusal or inability to consent.

Consent in an Emergency Situation:

An intervention should be initiated without consent when an emergency exists, except where an Advance Health Care Directive provides otherwise.

Where all the following criteria are fulfilled, consent is not required for treatment:

- a. There is an immediate threat to life, limb, or health.
- b. Treatment cannot be delayed
- c. The patient is unable to consent.
- d. For minors, the person who is legally capable of consenting on behalf of the minor is not available.

The physician must document the situation in the patient's health record.

The physician should seek a second opinion when feasible. If unable to do so, this fact should also be documented. A Consent Form is not required in such circumstances.

The clinical circumstances that necessitated emergency procedure without a signed consent should be documented in the interdisciplinary progress note by the main treating/attending physician or physician designer.

If a patient requires an urgent blood transfusion and there is no time to obtain consent, the transfusion should be carried out immediately. The attending physician or designated provider must document the clinical circumstances that required proceeding without signed consent in the interdisciplinary progress note.

It is good practice to inform a patient relations officer and document that all attempts were made to contact a substitute consent giver.

Telephone Consent:

A substitute consent giver can provide telephone consent, provided the elements of valid consent are present. Completion of Telephone Consent for Intervention Form.

Documentation on the Telephone Consent for Intervention Form should include the name of the person providing the information to the consent giver, name and identity number of the consent giver, and their relationship to the patient, date, time, summary of the information given, and the fact of consent (with limitations, if any).

The witness's participation and identity must be explained to the consent giver.

The witness can either listen via an extension telephone or speak to the consent giver following the initial conversation to verify that the consent process has taken place.

The witness verifies:

- a. The identity of the person giving consent.
- b. The patient on whom the intervention is to be performed
- c. The planned intervention
- d. That the consent giver acknowledges that adequate information about the procedure and alternatives has been given
- e. That the consent-giver gives consent voluntarily.

Telephone consents may be electronically recorded; if so, the consent giver must be informed that a recording is being made.

High Risk Consent:

In cases where the risk to the patient is deemed high, either due to the nature of the planned intervention or the natural course of the illness, a special type of consent should be obtained that clearly states the high-risk nature of the consent. This type of consent should only be obtained by the attending physician, and no delegation will be accepted. A witness must be present during the explanation of the high-risk aspects of the procedure and must sign the consent, including their full name and Identity number.

The cause of the high-risk status, as well as the associated high risks, including death, should be clearly stated

Consent Form Format:

All consent forms must be clear and legible and comply with all NHRA Policies and Standards.

All consent forms must include:

1. The name and address of the HCF.
2. The patient's name, identity number, and bar code label.
3. The name of the consent giver and the relationship to the patient.
4. The intervention for which the consent is given.
5. A list of disclosed risks along with the percentage of likelihood of occurrence.
6. The name of the physician or health care professional is responsible for the matter(s) for which consent is given.
7. A statement verifying that the consent giver understands and agrees to the procedure.
8. Specification of any limitation on consent.
9. The signature or mark of the consent giver.

10. The physician/health care professional's signature and official stamp verifying that the information was given and appears to have been understood.
11. The signature(s) of the witness and translator, if utilized.
12. The date of the signing of the Consent Form.

The currently used informed consent forms, which give a brief general statement that all the risks have been explained to the patient, will no longer be accepted.

6. APPENDICES:

Not Applicable

7. REFERENCES:

- Law No. (38) of 2009 establishing the National Health Regulatory Authority.
- Law No. (21) of 2015 on Private Healthcare Facilities in the Kingdom of Bahrain.
- Relevant regulations and circulars issued by NHRA.
- World Health Organization (WHO) – Patient Safety and Quality of Care Guidelines