nhra BAHRAIN

الهيئة الوطنية لتنظيم المهن والخدمات الصحية
NATIONAL HEALTH REGULATORY AUTHORITY

INFOREMD CONSENT POLICY

Leena AlQasem
7/31/2016

PROPOSAL FOR NATIONAL INFROMED CONDENT POLICY

Contents

PURPOSE

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

POLICY STATEMENT

The National Health Regulatory Authority (NHRA) support patient's right to participate in informed decision making, the exercise of 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 tradition and local custom in regards to consent.

SCOPE

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

TARGET AUDIENCE

Health care providers and all Health Care Facilities.

DEFINITIONS:

Adult:

A person/patient who has reached the legal age of 21 years.

Minor:

Any person who is below the age of 21 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.

Substitute Consent Giver:

A person may act as the consent giver in the event that the patient is unable to do so. This person is usually a close relative and should have familiarity with the patients 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 with respect to, that situation. In order to be valid, an advance health care directive must be signed and dated by the patient and a witness.

Physician:

All doctors including physicians and dentists

Attending Physician:

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:

Is the clear and explicit declaration of the patient of their willingness to undergo such interventions as specific medical examination, treatment or surgery.

General Consent to Treat:

A consent which gives the HCF the permission from the patient or 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 in the process of obtaining consent. 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 of the skin.

Invasive Procedures:

Any procedure that invades the bodily integrity of the patient and involves puncture or incision of the skin, the insertion of an instrument, injection of foreign material into the body, and may result in a reaction due to the administration of a drug or fluid, or 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 his will by intimidation or threats

RESPONSIBILITY:

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

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

Reception staff in primary care, polyclinics and 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 is for any diagnostic or therapeutic invasive procedure that has material or specific risks. Material or specific risks exist when the information provided would cause a reasonable person to have to make a decision regarding 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 prior to examination, or an agreement of the patient to certain treatment plans.

Written consent:

This type of consent is reserved for any diagnostic or therapeutic intervention that invades the bodily integrity of the patient. It is the responsibility of the 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.

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 competency of the patient, except where there is contrary evidence, and thus respect the right of the patient to decide what is or is not to be done to his or her body.

The competency of any patient, when doubted, is decided on the basis of whether or not the patient is capable of understanding the nature and consequences of a treatment decision and not on 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 the capacity of a patient to make a treatment decision is responsible for assessing the patient's situation and documenting their professional judgment or requesting the advice of another more senior person or a different specialty.

3. Disclosure of information:

Certain information needs to be disclosed to the patients or their guardians prior for them giving their informed consent to be treated. The disclosure of information may be verbal or written. Other methods of disclosure may be used such as video tapes, or CD's. This information includes:

3.1. Diagnosis and nature of illness:

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

3.2. Nature and Purpose of Proposed Intervention:

The health care provider informs the consent giver of the details about the nature of the proposed intervention, the justification for it, and what it is supposed to accomplish.

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, and risks with high probability and minor or grave consequences, are to be disclosed.

3.3. Reasonable Alternatives:

The treatment alternatives, if any exist, 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. Expected immediate short-term and long-term impacts of treatment on the patient's lifestyle are to 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 part of the consent process, the patient and their guardian must be informed about the nature and consequences of refusal to submit 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 problems to be encountered by refusing treatment are all well understood by the patient.

3.5. Who is to perform the procedure:

The Health care provider should inform the patient of the likelihood that performing the procedure may involve a number of qualified healthcare professionals. Where the facility

is a teaching hospital, 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 has to assess the level of understanding of the patient or their guardian of the information presented to them regarding the proposed intervention. If the patient or their guardian do not understand the information presented to them or they have misconceptions about certain aspects of the intervention for example overestimated rate of success of dismissal of grave risks, more effort should be placed on correction of 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 interventions deemed necessary in the course of treatment as determined 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 is contingent on good 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 open and sustain good communication and to 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. Discretion on the part of the physician allows for the presentation of accurate information with a minimum of influence. The goal for physicians ought to be to present the pertinent information in a way that allows the consent giver to reach an independent and 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, invalidates the authorization. Misrepresentation can be in the form of well-intentioned exaggeration, distortion, or trivializing of essential information.

WITNESSING CONSENT:

The witness for the consent must be someone other than the primary operator for the intervention. The signing witness must witness the discussion of the procedure as well as the signing of the forms. When a translator is required, the translator should function as a witness.

DURATION AND VALIDITY OF 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 signature and date from the attending physician and consent giver.

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 consent of the patient to receive blood components, remains valid any time during the patient's hospital stay. However patients or Substitute consent giver must be informed of each required transfusion.

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

2. Duration Exception for Dialysis:

Consents for dialysis remain valid, unless revoked by the patient, throughout the course of 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 a valid consent was absent.

Exceptions:

In accordance with local law and cultural tradition: Only the procedures involving reproductive interventions for female patients require informed consent of the patient as well as the husband or legal cultural guardian regardless of age

SUBSTITUTE CONSENT GIVER FOR INCOMPETENT ADULTS:

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

In order to help ensure that any treatment or procedure that normally would require consent is not performed inappropriately, a substitute consent giver must be asked to consent for the incompetent patient. 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 sequence of priority 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 who 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 listed.
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 as to the competence of a patient, consultation should be sought from a specialist in the neurosciences, specifically a neurologist or psychiatrist as is 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 for a child as minors lack 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 the emergency or urgent situation where the father is not present at that time. (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 (from father's side then from mother's side), Grandfather, Grandmother, Other relatives from father's side, then other relatives from mother's side.

4. Legal Guardian:

A legal guardian may give consent for the minor. Typically this would be a case where the child lives with grandparents or other family members who have legal guardianship status by 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, babysitters, etc. must have authorization from the proper guardian before they can give 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 case that is non-emergency and the guardian cannot be contacted, treatment is initiated in the best interests of the patient, and treatment continues until the consent giver is available. In such a case, it is good practice to inform the patient's relation officer in 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 being treated.
c. What it means 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, having lawful custody, must authorize a temporary caregiver, in writing, to consent to 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 without written authorization from 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, persons 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 persons.

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 the time of 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 reasoned 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 particular patient. This presumes that the physician providing the information is familiar with the patient's history, especially the 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 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 counter signed 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 a 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 in the patient's health record by the physician obtaining consent.

Exceptions:

a. In accordance with cultural tradition: Only the procedures involving productivity in female patients require informed consent of both the patient and the husband or legal cultural 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 and 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 on the consent form in the appropriate section. If the patient is unable to sign, have the legal/cultural representative person sign 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 help to educate the patients and complement 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 physician to delegate, to another physician must extend only to the one named as a delegate. Such delegation must be documented on 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 holds the ultimate responsibility 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 and may choose among different treatment alternatives or may 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 the fact that the information was given.

Ideally, when treatment is refused, a Refusal of Treatment form, should be signed by the patient.

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 **three consultants** within the institution in order to perform the intervention.

b. Where one relative consents to an intervention, and another relative refuses, it is permissible to rely on the consent, but it is preferable to obtain consent from three consultants.

c. The individual patient has, as a competent adult, prepared an advance health care directive specific to the intervention.

OBTAINING GENERAL CONSENT TO TREAT:

The admissions department for the hospital is responsible for obtaining the general consent for treatment.

The patient and or legal representative must be given the 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 his or her legal name on the consent form in the appropriate section. If the patient is unable to sign, have the authorized person sign on his or her own behalf. The legal representative must sign and indicate their relationship to the patient.

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

If the patient or guardian refuses or was not able to consent, at the bottom of the consent should be documented that the patient refused or was not able to give consent.

Consent in Emergency Situation:

An intervention should be initiated without consent when an emergency situation exists, **except where there is an Advance Health Care Directive contrary to the intervention.**

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

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

The physician must document the situation on 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 designee.

If the patient’s emergent need for blood and his blood components does not permit obtaining consent, the transfusion should proceed without delay and the clinical circumstances that

necessitated emergency transfusion without a signed consent should be documented in the interdisciplinary progress note by the main treating/attending physician or physician designee.

It is good practice to have a patient relation officer informed and document the fact that all attempts were made to contact a substitute consent giver.

TELEPHONE CONSENT:

A substitute consent giver can give telephone consent provided the elements for a 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 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 participation and identity of the witness must be explained to the consent giver.

The witness can either listen through the use of an extension telephone or speak to the consent giver following the initial conversation to verify 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 the consent voluntarily.

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

CONSENT FOR SEROLOGICAL TESTING FOR HIV AND HEPATITIS:

Consent is required for HIV, hepatitis B, hepatitis C and HTLV testing, when performed for screening purposes, and must be documented in the patient's clinical record

Consent must be obtained by the attending physician regarding the risks, harms and benefits of being tested.

For children and incompetent adults, informed consent must be obtained from the parent or substitute consent giver.

HIGH RISK CONSENT:

In cases where the risk to the patient is deemed to be high either due to the nature of the intervention planned or due to the natural course of the illness, a special type of consent should be obtained which clearly states high risk consent on it.

This type of consent should only be obtained by the attending physician and no delegation will be accepted.

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 name, file number, and bar code label.
3. The name of the consent giver and 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 responsible for the matter(s) for which consent is given.
7. A statement verifying 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.