


Health Authority – Abu Dhabi		هيئة الصحة - أبوظبي
Division/Department/Section: PPR/HCP Title: Consent Policy	Reference Number: PPR/HCP/P0003/09 First Issue Date: January 2007 Revised: July 2009 Revision Date: July 2011 Version: 2	

1. PURPOSE

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

2. POLICY STATEMENT

Health Authority Abu Dhabi (HAAD) 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.

HAAD mandates that all Health Care Facilities (HCFs) 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 HCFs must respect social tradition and local custom in regards to consent.

3. SCOPE

Consent applies to all treatment/procedures outlined in this policy.

4. TARGET AUDIENCE

Health care providers and all entities involved in research involving human subjects.

5. RESPONSIBILITY

It is the responsibility of the main attending physician and/or his or her physician designee to obtain an appropriate informed consent before a surgical, diagnostic, or invasive procedure or to obtain appropriate informed consent prior to a subject being admitted into a research study. Where research is being undertaken, the principle research investigator is responsible to obtain appropriate informed consent consistent with the HAAD Policy [Policy Governing (Medical) Research involving human subjects].

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

Reception staff in primary care, polyclinics and Emergency Room (E.R.) will be responsible for obtaining General Consent for Treatment.

6. DEFINITIONS AND ABBREVIATIONS

Adult	A person/patient who has reached the age of 18 years.
Advance health care directive	A document that describes a clinical situation and clearly states the patient understands of, 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.
Attending Physician	Physician who is responsible for the overall care of a patient.
Consent	A declaration (written or oral) of willingness to undergo a procedure, treatment or other intervention. Consent is normally "informed", that is, given only after receipt and understanding of all relevant information regarding the risks and benefits of the proposed treatment(s).
Consent for Research	An informed consent for a subject and or his legal/cultural representative to give informed consent for participation in research projects at licensed facilities.
E.R	Emergency Room.
Foreign Resident	A foreign resident is a person who is present in the United Arab Emirates and is not a citizen of the United Arab Emirates.
HAAD	Health Authority Abu Dhabi
General Consent to Treat	A consent which gives the hospital 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.
Informed Consent	Prior to the performance of a procedure and/or treatment, the patient or legal guardian, who is authorized to consent on behalf of the patient must be told about the procedure, the inherent risks, its benefits and alternative methods, of treatment, the consequences of non treatment, any expected result or outcome of treatment and the name of the physician(s).

Invasive Diagnostic Procedure	<p>The performance of a diagnostic procedure may be comparable to an operative or invasive procedure in that it may:</p> <p>Involve a hospital defined invasive procedure requiring informed Consent.</p> <p>Result in a reaction due to the administration of a drug or fluid, or</p> <p>Places the patient at risk</p> <p>A medical procedure that invades (enters) the body, usually by cutting or puncturing the skin or by inserting instruments into the body.</p>
Junior Medical Staff	<p>Any physician employed by the health center primarily in a service capacity, which is supervised and responsible to a member of the consultant Medical Staff. This includes, but is not restricted to, House Officers, Senior House Officers, Registrars and Senior Registrars.</p>
Legal/Cultural Guardian	<p>A person who is authorized to consent based on UAE national law and/or local culture.</p>
Medical Trainee	<p>Any health care professional or student in a health care discipline, who is performing a training rotation in the health center. This includes, but is not restricted to Medical Students, Interns, Residents, Fellows, Registrars and Senior Registrars.</p> <p>These trainees are supervised by and responsible to a member of the Consultant Medical Staff</p>
Minor	<p>Any person who is not an adult.</p>
Non-invasive procedure	<p>A diagnostic effort or treatment that does not require entering the body or puncturing the skin. Or procedures that do not require insertion of an instrument or device through the skin or bodily orifice for diagnosis or treatment.</p>
Physician	<p>Within these policies, all references to "physicians" shall be deemed to include physicians and dentists.</p>
Substitute consent giver	<p>A person who may act as the consent giver in the event that the patient is unable to do so.</p> <p>This person is usually a close relative and should have familiarity with the patients presumed wishes regarding medical care.</p>

I. **CONSENT:**

Consent is required for all interventions, procedures or treatments except where authority to treat is granted under appropriate legislation e.g. a mental health act, or a court order.

Consent may be implied or explicit, in accordance with the following definitions:

Implied Consent is established when a patient's conduct indicates a willingness to submit to general medical treatment such as basic skin care or monitoring of vital signs.

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 is established when a patient declares his willingness to undergo and authorizes such interventions as specific medical examination, treatment or surgery.

Explicit consent should be written and signed on the "Consent for Surgery or Special Procedure Form".

In the case of a "minor" (less than 18 years of age, see Section "Definitions"), the concepts of Implied Consent are applied to the "Substitute Consent Giver" (see Section "Definitions"). (Also see Section, "Substitute Consent for Minors").

Resources Required:

Consent Forms, Information brochures/pamphlets/media as appropriate, ink pens, and an interpreter as appropriate. Also, at times a Patient Relations Officer and /or legal advice may be needed.

Explicit consent

All explicit consent must be documented in the patient's health record.

Procedure:

A "Consent for Surgery or Special Procedure" form must be used if the proposed intervention is for any surgical, operative or diagnostic intervention 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 to proceed with a particular intervention

Research

All consent for the involvement of a human being as a subject for clinical research must be explicit and should be in line with HAAD Policy [Policy Governing (Medical) Research involving human subjects].

II. Elements of a valid consent

Policy:

Consent is valid only when the seven critical elements of a valid consent are present.

The seven critical elements are:

1. Competency (decision making ability)
2. Capacity to make treatment decisions
3. Disclosure of information
4. Specificity
5. Opportunity for questions and answers
6. Voluntariness
7. Accuracy

Explanation:

1. Competency: (decision making ability)

This refers to the 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 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.

2. Capacity:

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.

3. Disclosure of Information:

3.1. Nature and Purpose of Proposed Intervention:

The health care provider informs the consent giver of the details of the intervention. The health care provider discloses information to the consent giver pertaining to the justification for the intervention 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. 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. 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:

This logical extension of the principles of consent, and part of the consent process, requires that the patient know the nature and consequences of refusal to submit to tests or treatment. 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 that the facility is a teaching hospital (is this the case with all hospitals? Or is this a likely case? If the latter, I suggest that the sentence be edited to read as follows: "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, house officers, registrars and/or other health care students may participate in interventions under the supervision of fully qualified professionals".

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. Specificity:

The consent authorization must be specific for the procedure 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 to be necessary in the course of treatment as determined by the treating physician/specialist. The consent must include the specific procedure, sub-procedure and variations of

the procedure.

5. 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.

6. Voluntariness:

Consent must be free of undue influence and coercion.

Discretion on the part of the health care provider allows for the presentation of accurate information with a minimum of influence. The goal for health care providers 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.

7. Accuracy:

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

The health care provider must always give accurate information about proposed treatments. Intentional withholding of information, like coercion and undue influence, invalidates the authorization. Misrepresentation can be in the form of well-intentioned exaggeration, distortion, or trivializing of material information.

III. Witnessing Consent

Policy:

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.

IV. 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:

- It is withdrawn by the consent giver; or
- A change is made in the planned and consented to intervention; or
- 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/ health care provider is responsible for ensuring that the consent remains valid from the time of consent to the commencement of the intervention.

V. Consent to treat is required for

Each Emergency room visit and for each hospital admission (of any length)

For Ambulatory care (Poly Clinic, Dental Center, etc), a signed Consent to Treat will suffice for all subsequent visits

Duration Exception

Blood Components consents:

Once obtained, are valid any time during the patient's hospital stay. However patients or Substitute consent giver must be informed of each required transfusion.

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

Duration Exception for Dialysis:

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

VI. Consent Giver

Policy:

An adult individual (**18 years**) of age or older 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. (See Section "Elements that Constitute a Valid Consent")

An adult female may sign her own consent.

Consent for those less than 18 years of age should be signed by the father, legal guardian, or Substitute Consent Giver.

EXCEPTIONS:

In accordance with local law and cultural tradition: Only the **procedures involving reproductivity in female patients require informed consent of the husband or legal cultural guardian regardless of age**

VII. Substitute Consent Giver for Incompetent Adults

Principle:

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. One such situation would be the taking of consent 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.

Policy:

When an adult is assessed as incompetent to consent for a procedure, treatment or other intervention, a substitute consent giver must be sought. **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 not incompetent (was competent). Ideally this appointment will be in writing and witnessed.
2. A guardian appointed by a court that has jurisdiction in Abu Dhabi or elsewhere in the United Arab Emirates.
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 above.

If, however, consent is refused, such a consent giver will be the final authority for the purposes of this policy. Please also see Section "Refusal of Consent for a Minor or Incompetent Adult".

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.

VIII. SUBSTITUTE CONSENT GIVER FOR MINORS

Policy:

Substitute consent givers for minors (under the age of 18 years) are expected to act in the best interests of the minor. The substitute consent giver must have assumed guardianship of the minor.

The father consents for a child when he or she is a minor and therefore lacks the capacity to consent for himself or herself. **(Father can consent for his children even if the father is less than 18 Years of age).**

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.

The mother can consent for a child in the emergency or urgent situation that 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.

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. An authorized Court of Law is one that has jurisdiction in the child's country of origin.

Minors in Government Homes: The Crown Prince / Sharia Court or its delegate is the proper person to give consent if the child is a permanent ward.

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.

Incompetent parent (or guardian):

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

- The information and opinion given.
- The condition being treated.
- What it means to refuse treatment.
- And the proposed treatment.

In this case an alternate consent giver will be chosen. (See "Substitute Consent Giver for Incompetent Adults").

IX. AUTHORIZATION BY GUARDIAN FOR TEMPORARY CAREGIVER**Policy:**

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 child 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.

X. CONSENT FOR TEMPORARY ABSENCE FROM THE HOSPITAL**Policy:**

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

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

XI. CONSENT FOR DISCHARGE OF A MINOR UNESCORTED BY GUARDIAN**Policy:**

Consent must be obtained from the father/ guardian for the discharge of a minor child 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.

XII. CONSENT FOR SURGICAL AND/ OR INVASIVE PROCEDURE**Policy:**

The physician who is to perform a procedure for which consent is considered necessary (see "Consent") 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 on 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 surgeon, 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.
- 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 true emergencies obtaining a valid consent is not necessary (see Section "Consent for Emergency Intervention").
- 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.
- k. An adult female may sign her own consent.

EXCEPTIONS:

- a. In accordance with local law and cultural tradition: Only the procedures involving reproductivity in female patients require informed consent of 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 (18 years or less) must be signed by the father. If the father is not present, see Section "Substitute Consent for Minors".
- 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.

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. Surgical and/or invasive procedures should be legibly printed and must state the exact location (for example right or left side).

If the patient has questions regarding the procedure, the outcome or alternatives, notify the physician or surgeon before proceeding.

- g. Questions regarding preparation, nursing care, etc. may be answered by the nurse.

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:

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.

Note:

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.

XIII. DELEGATION AND SUB-DELEGATION OF INTERVENTIONS**Policy:**

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 (including a member of the junior medical staff or a medical trainee) is competent and qualified to perform the procedure or treatment.

The attending physician is responsible when the delegation is to a non-licensed physician.

XIV. SUPERVISION OF JUNIOR STAFF AND MEDICAL TRAINEES

Policy:

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.

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

XV. REFUSAL OF CONSENT

Principles:

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 patient may choose among different treatment alternatives or may refuse all forms of treatment.

Policy:

A competent adult has the right to refuse any intervention, 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.

The physician must document in the patient's health record the fact that the information was given.

Ideally, when treatment is refused, the Refusal of Treatment, Blood or Blood Products form ...etc should be signed by the patient.

XVI. REFUSAL OF CONSENT FOR A MINOR OR FOR INCOMPETENT ADULT BY GUARDIAN

Principles:

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.

Policy:

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.

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

EXCEPTIONS TO THIS POLICY:

- 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 apply to the Competent Court for the purpose of obtaining, consent.
- b. Where one relative consents to an intervention, and another relative refuses it, it is permissible to rely on the consent, but it is preferable to obtain consent from the Competent Court.
- c. The individual patient has, as a competent adult, prepared an advance health care directive specific to the intervention.

XVII. ADMISSION TO HOSPITAL**Policy:**

Forms that address the following issues must be completed upon admission to hospital.

- General Admission Consent (General Consent to Treat)
- Responsibility for personal belongings
- Advance health care directive
- Patient Confidentiality

Obtaining General Consent to Treat:

- a. The admissions department for the hospital is responsible for obtaining the general consent for treatment.
- b. The patient and or legal representative must be given the General Consent on presentation to the appropriate admissions area.
- c. The consent is provided in Arabic and English and an interpreter is available if needed.
- d. 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.
- e. A Thumb print can also be used instead of signature if the patient is unable to write a signature.
- f. 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.

XVIII. FOREIGN RESIDENT AGREEMENT

I.....
Name of Consenting Party
of.....
Address

Agree that the relationship between theHospital/ Medical Center, and me shall be governed and construed in accordance with the laws of the United Arab Emirates.

I Acknowledge that any or all investigations, procedures and/ or treatments will be performed in the United Arab Emirates and that the Civil Court of the Country shall have jurisdiction to entertain any complaint, demand, claim or cause of action, whether based on alleged breach of contract or alleged negligence arising out of the above noted investigation, treatment or operative procedure.

I hereby agree that I will commence any such legal proceedings in the United Arab Emirates and only in the United Arab Emirates, and I hereby submit to the jurisdiction of the Civil Court of the United Arab Emirates.

Signature of Consenting Party

Name of Consenting Party

Signature of Translator

Name of Translator

XIX. CONSENT IN EMERGENCY SITUATION

Policy:

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:

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

Procedure:

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.

X. TELEPHONE CONSENT

Policy:

A substitute consent giver can give telephone consent provided the elements for a valid consent are present (see Section "Elements of a Valid Consent").

Procedure

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:

- The identity of the person giving consent.
- The patient on whom the intervention is to be performed
- The planned intervention

- That the consent giver acknowledges that adequate information about the procedure and alternatives has been given
- 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.

XXI. CONSENT FOR SEROLOGICAL TESTING FOR HIV AND HEPATITIS

Policy:

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

Requirements:

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.

XXII. CONSENT FOR RESEARCH

Policy:

Consistent with the HAAD Policy [Policy Governing (Medical) Research involving human subjects], no investigator may involve a human being as a subject into clinical research unless the investigator has obtained Informed Consent from the subject or the subjects legally authorized representative.

- a. The elements of a valid Informed Consent shall include:
 - a statement detailing the purpose of the research, the expected duration of the Subject's participation, a description of any procedures to be followed and identification of any procedures that are experimental;
 - the treatment(s) included in the research and the probability of random assignment to each treatment;
 - a description of any foreseeable risks and benefits to the subject, and when applicable an embryo or fetus carried by the subject or to the subject's nursing infant;
 - if the investigation involves more than minimal risk, an explanation as to whether any compensation and/or medical treatments are available if injury occurs to the subject must be disclosed and if so, what they consist of;
 - a disclosure of any appropriate alternative procedures or courses of treatment;
 - the subject's responsibilities with respect to the research;
 - a statement describing how confidentiality will be maintained or private information identifying the subject;
 - a statement addressing direct access to the subject's medical records by the REC, auditors, HAAD Research Council and any agents of each, for the verification of the procedures and/or data associated with the clinical research;
 - a statement detailing the person(s) to contact for further information regarding the clinical research, the subject's rights, and whom the subject should contact in the event of injury arising in conjunction with the clinical research;
 - a statement that the subject's participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is entitled; and
 - a statement addressing cultural and religious concerns/indications, if applicable.
- b. As appropriate, additional elements of informed consent are as follows:
 - a statement that the particular treatment or procedure may involve risks to the subject (or embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable;

- anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
 - any additional costs to the subject that may result from participation in the clinical research;
 - the consequences of a subject's decision to withdraw from the clinical research and procedures for orderly termination of participation by the subject; and
 - a statement that significant new findings developed during the course of the Clinical Investigation and that may relate to the subjects willingness to continue participation will be provided to the subject.
- c. The REC may approve informed consent documents that do not include all of the elements as stated, or may waive the requirement for obtaining informed consent provided the REC finds and document that:
- no more than minimal risks to the subject, and;
 - the waiver or alternation will not adversely affect the rights and welfare of the subjects, and;
 - the clinical research could not practicably be carried out without the waiver or alteration; and
 - whenever appropriate, the subjects will be provided with additional pertinent information after participation.
- d. Except in approved cases, informed consent shall be documented by use of a written consent form approved by the REC and signed and dated by the subject or the subjects legally authorized representative and the investigator (or study staff if approved by the REC) who obtained the consent:
- a signed and dated copy of such form shall be given to the person signing the form;
 - the consent form may be either if the following:
 - a written consent document that embodies the elements as stated in this policy; or
 - a short form written consent document stating that the elements of informed consent required by this policy, have been presented orally to the subject or the subject's legally authorized representative; provided that there is a witness to the oral presentation approved by the REC.
- e. Obtaining informed consent from specific groups of individuals that include, but are not limited to the following, will require additional elements for obtaining and documenting informed consent, as provided in HAAD research procedures:
- individuals with impaired mental capacity;
 - children;
 - non-English speaking Subjects; and
 - illiterate English speaking Subjects
- f. The requirement for informed consent shall be deemed unfeasible or impracticable when all of the following conditions pertain:
- the subject is confronted by a life-threatening situation necessitating the use of the investigational product;
 - the subject is incapable of communicating with the investigator due to his diseased condition;
 - time is not sufficient to obtain consent from the subject's legally authorized representative;
 - there is no available alternative method of approved or generally recognized therapy that provides equal or greater likelihood of saving the life of the subject.
- g. If the immediate use of the investigational/research product without the consent of the subject or the subject's legally authorized representative is, in the investigator's reasonable opinion, required to preserve the life of the subject, both the investigator and a physician who is not otherwise participating in the clinical research must certify in writing that all of the above conditions in Section 34 are met and must submit the required documentation to the REC within five (5) working days.
- h. The REC may approve a proposal for clinical research without obtaining informed consent from all of the subjects if the REC finds and documents each of the following:

- the prospective subjects are in a life-threatening situation, available treatments are unproven or unsatisfactory and the collection of valid scientific evidence, which may include the use of placebo, is necessary to determine the safety and effectiveness of a particular intervention;
 - obtaining informed consent is not feasible because:
 - the subjects are not able to give their informed consent due to their medical condition;
 - the intervention under investigation must be administered before consent from the legally authorized representative is feasible;
 - there is no reasonable way to identify prospectively the individuals likely to become eligible for participation in the clinical research.
 - participation in the clinical research holds out the prospect of direct benefit to the subjects;
 - the clinical research could not practically be carried out without the waiver of the obligation to obtain informed consent;
 - additional protections of the rights and welfare of the subjects will be provided, including at least the establishment of an independent data safety monitoring board to exercise oversight of the clinical research.
- i. The REC may waive the requirement to document informed consent with a signed written informed consent document for some or all subjects associated with a clinical research study if it finds one of the following:
- the only record linking the subject and the clinical research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject shall be asked if he wants documentation linking him with the clinical investigation and his wishes shall govern.
- j. The informed consent requirements in this policy are not intended to exclude any applicable institutional policies that may require additional information to be disclosed for informed consent.

Obtaining Consent for Research:

It is the responsibility of the physician or principal investigator conducting research to obtain appropriate explicit informed consent for subjects who wish to be included in research.

XXIII. CONSENT FOR NON-PHYSICIAN INTERVENTIONS

Policy:

Some therapies and diagnostic interventions, as identified by departments, programs and disciplines, provided by non-physician health care professionals require valid consent.

The health care provider who is to perform the procedure is responsible for ensuring that all relevant information is provided to the consent giver in a setting conducive to an independent and reasoned decision. This health care provider must be capable of answering questions regarding the intervention and the implications of the intervention for the particular patient.

Procedures:

The health care provider informs the patient of the intervention, its attendant risks and benefits, and then acquires and documents the consent.

A consent form is required for specific interventions as a record of the patient's understanding and agreement.

The completed form becomes part of the patient's permanent health record.

Consent should be obtained in a suitable environment, with adequate time to discuss the details of the procedure.

If the patient has been pre-medicated (with analgesic, sedative or other drugs that may alter his or her ability to understand or make decisions) he or she must be assessed by a physician, regarding his or her capacity to make a rational decision and to give valid consent.

The health care provider who obtains the consent must enter documentation of these circumstances in the patient's health record.

A consent form must never be completed after the intervention has taken place. **An Incident Report** must be prepared in the event of an intervention being completed without proper consent.

Alterations on a completed consent form must be made before the intervention commences and the alterations must be signed and dated by the consent giver and the health care provider. Notation of the alteration and the reason for it must be made in the patient's health record.

Note: Information provided through programs such as patient teaching, videos and literature help to educate the patients and complement the information provided by the health care provider. However, it is not intended to replace the information exchange between the health care provider and the consent giver.

XXIV. CONSENT FOR NON-THERAPEUTIC ACTIVITIES

Policy:

Activities that may compromise an individual's privacy, confidentiality, or health and safety require specific consent (examples: audio/visual recording, media interviews, release of records, photos).

XXV. CONSENT FORM APPROVAL PROCESS

Policy:

All consent forms must comply with the current HAAD Policy.

Development of proposed and revised consent forms is the responsibility of the Consent Policy Committee.

Departments, programs or services may develop and propose new consent forms or enhance versions of existing forms and present them to the Consent Policy Committee.

XXVI. CONSENT FORM FORMAT

Policy:

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

All consent forms must include:

- The name and address of The Hospital / Medical Centre.
- The patient name, file number, and bar code label.
- The name of the consent giver and relationship to the patient.
- The intervention for which the consent is given.
- A statement to verify discussion of risks and benefits of the procedure.
- The name of the physician or health care professional responsible for the matter(s) for which consent is given.
- A statement verifying the consent giver understands and agrees to the procedure.
- Specification of any limitation on consent.
- The signature or mark of the consent giver.
- The physician/health care professional's signature verifying that the information was given and appears to have been understood.

- The signature(s) of the witness and translator, if utilized.
- The date of the signing of the Consent Form.