هيئة الصحة
HEALTH AUTHORITY

HAAD GUIDELINES FOR PATIENT CONSENT

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Table of Contents

INTRODUCTION

Consent before treatment is a legal requirement and is an important part of the discussion and decision-making during the provision of health care services. Physicians and allied health care professionals should work in partnership with their patients and discuss with them their condition and treatment options in a way that can be understood by the patient. Physicians and health care professionals should always respect the patient's right to make decisions about their care.

Written Consent is not needed for simple diagnostic tests, screening services non-invasive or routine procedures. Consent is assumed implied for example, where the patient allows the doctor to draw a blood sample for lab tests. This is however; different from a treatment that puts the patient in a vulnerable position or can possibly cause serious harm. In such cases patients should be provided with information in order to weigh up their options, consider risks before reaching a decision whereby written Consent shall be sought

Even when there are no other accepted medical treatment options, it is the patient's right as a competent adult or as the Substitute Consent Giver to refuse a treatment or seek alternative treatments.

ABOUT THIS GUIDELINE

There are a number of UAE Federal and Abu Dhabi Laws, Decrees and Policies that govern Consent in the Health Care setting (Appendix A). This document serves as a guideline for physicians and allied Health Care professionals to implement the Consent as per HAAD Regulation and UAE Laws and sets out best practice for physicians and allied health care professionals to obtain Consent before:

- undertaking any examination or investigation
- providing interventions or treatment
- involving patients in teaching and/or research

This guideline is not and cannot be exhaustive therefore physicians and allied health care professionals should use their own judgement and apply the principles for Consent to address specific case scenarios.

Who is this Guideline for?

All HAAD Licensed Physicians, Allied Health Care Professionals and Health Care Providers in the Emirate of Abu Dhabi are required to understand the Law and Regulations as it applies to them and where they work

1. PURPOSE

The purpose of this guideline is as follows:

- To set out the principles to patient Consent that are important during the provision of clinical interventions and treatment
- To advise on the best practice for obtaining Consent for health care procedures, anaesthesia, research and other activities in the field of patient care
- To provide a framework for good practice that covers the various situations that physicians and allied health care professionals may face in their day to day work in regards to consent
- To identify practices that support patient rights to participate in informed decision making, the process by which accurate and adequate information should be disclosed for relavant medical procedures, interventions or treatments
- To recommend measures that Health Care Facilities (HCFs) should take to provide patients and those authorised to make decisions on their behalf/Substitute Consent Givers with information that will enable them to fully participate in medical treatment decisions
- To respect local custom in regards to patient consent

This Guideline should be read in conjunction with Appendix A and B. This guideline does not include Physician, Health care Professionals or Health Care Facilities responsibilities to protect personal information about their patients.

2. DEFINIITIONS

Category	Definition
Consent	A declaration of willingness to undergo a procedure, treatment, intervention or investigation which is evidenced in the patient record or.
Informed Consent	Informed Consent is established when a patient (or Substitute Consent Giver) following consultation with the physician and/or health care professional declares his/her willingness to authorise and undergo a procedure, intervention or treatment. Informed Consent takes place when the patient is informed about the inherent risks, its benefits and alternative methods of the intervention or treatment, the consequences of non-treatment, any expected result or outcome of treatment and the name of the physician(s) and/or health care professionals who will be performing the procedure, intervention or treatment. Informed Consent usually evidence by written documentation from both the patient and/or the Substitute Consent Giver and/or physician and/or health care professional.
Implied Consent	Implied Consent is established during consultation with the physician and/or health care professional on their health status and when the patient and/or a Substitute Consent Givers conduct indicates a willingness to submit to general medical treatment *which has minimal risk* such as screening tests, prevention programmes, monitoring of vital signs, general administration of ongoing treatment, diagnosis an emergency department or clinic, assessments and examination, laboratory tests, radiology and other appropriate non-invasive procedures that are considered to be routine in the provision of patient care.
Substitute Consent Giver	A person who is authorised to Consent for another person based on UAE Law. A person who may act as the Substitute Consent Giver in the event that the patient is unable to do so. This person is ideally a close relative and should have familiarity with the patients presumed wishes regarding their medical care. In accordance with the Law the Substitute Consent Giver can be: • A relative up to the fourth degree in the following order of priority: father, mother, husband, wife, son, daughter, grandfather, grandmother, son's children, daughter's children, paternal uncle, paternal aunt, maternal uncle, maternal aunt, paternal' s uncle children and maternal aunt's children • A court appointed guardian in UAE or elsewhere • A parent for a minor (less than 18 years of age) • The father even if he is less than 18 years of age • In the absence of the father the mother can give Consent even if she is less than 18 years of age • If the Substitute Consent Giver is deemed incompetent an alternate Consent Giver should be sought

Category	Definition
Consent for Research	An Informed Consent given by the Patient and/or Substitute Consent Giver to give Informed Consent for their participation in research projects at a HAAD licenced research facility.
Incompetent Patient	A patient may be judged incompetent by a physician or allied health care professional if, for any reason, it is felt that they are 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 (alcohol or medications), acute disturbances of consciousness, impaired reasoning or memory loss caused by disease/injury validated by clinical assessment.
Adult	A person or patient who has reached the age of 18 years.
Minor	Any person or patient who is less than 18 years of age.
Physician	Physicians and Dentists licensed by HAAD who are authorised with in their scope of practice to provide preventive, curative, promotional or rehabilitative health care services in an evidenced and systematic way to individuals, families or communities.
Most Responsible Physician	Physician who is responsible for the overall care of a patient.
Consultant, Specialist or General Practitioner	As per the HAAD Pre-Qualification Requirements
Health care Professional	Is a HAAD licensed health care professional authorised within their scope of practice to provide preventive, curative, promotional or rehabilitative health care services in an evidenced and systematic way to individuals, families or communities.
Medical Trainee	Any health care professional or student in a health care discipline, who is performing a training rotation in a health care facility. This includes, but is not limited to: Medical Students, Interns and Residents. Trainees are supervised by and responsible to a member of the Consultant Medical Staff Team.
Invasive Diagnostic Procedure	A medical procedure that invades (enters) the body, usually by cutting or puncturing the skin, mucous membranes or connective tissue and/or by inserting instruments into the body orifices. The performance of an invasive diagnostic procedure may be comparable to an operative or invasive procedure in that it may: • Involve a hospital defined invasive procedure; • Result in a reaction due to the administration of a drug or fluid; and • Places the patient at risk of harm

Category	Definition
Emergency Life Threating Cases	A medical emergency is an injury or illness that poses an immediate risk to a person's life or long term health.
Patient Medical Record	A collection of documents (may include electronic) which provide an account of each episode in which a patient visited or sought treatment and received care or a referral for care from a health care facility. It contains information such as; the assessment of the patient's Consent form, health status, the health history, laboratory and radiologic reports of tests performed, notes by physicians and/or health professionals regarding the daily condition of the patient, as well as order sheets, medication sheets, admission records, discharge summaries, and other pertinent data. The record is confidential as per UAE Law and is held by the health care facility.

3. CONSENT AND NEED FOR CONSENT

Consent is a declaration of a person's willingness to undergo a procedure, treatment, investigation or other intervention. Consent is needed as an ethical instrument demonstrating the right of the patient to control his/her health care and the physician's ethical duty to involve the patient in his/her care. Consent evidences voluntary choice of treatment by the competent patient whose treating physician had disclosed all information necessary for the decision-making.

4. INTERVENTIONS FOR CONSENT

- Appropriate Consent should be obtained prior to any procedure, intervention or treatment
- Consent applies to all decisions about care including, treatment of minor and self-limiting conditions, treatment of major interventions with significant risks of side effects, investigations and screening services. This includes:
    - When treatment is surgical and requires general anesthesia. It is recommended for Consent be sought by the surgeon and the anaesthetist. The surgeon may seek Consent for anaesthesia if he/she is authorised by health care facility to do so
    - When treatment is surgical and does not require general anesthesia
    - When treatment involves radiotherapy and/or chemotherapy
    - When treatment or investigation involves endoscopic procedures
    - When treatment is deemed high risk (or increases in risk following each treatment) and is planned for more than one session. In such cases, Consent should be sought for each treatment session

    - When treatment is for reproductivity and fertilisation in female patients.
    - Following stabilisation of an emergency Life Threatening Case i.e. the physician must in the first instance provide the necessary treatment to save the patient's life and prevent serious deterioration of the patient's condition
    - In non-emergency cases where the patient is unconscious and the legal Substitute Consent Giver is not available, the physician shall consult with at least one other physician prior to treatment
- Clinical examination: as per Federal Law a physician *may not* conduct a clinical examination without the Consent of the patient
- Clinical examination of the opposite gender: as per Federal Law a physician may not conduct clinical examination of the opposite gender unless the following two conditions are met:
    - The patient Consents, unless it is impossible to obtain such Consent due to the patient's physical, psychological or mental condition or for any other reason
    - The presence of a third person, unless the presence of a third person is not possible after the physician has made every effort to bring in a third person and the patient consents to undergoing the clinical examination without such third person
    - Emergency Life Threatening cases are exempted from the aforementioned conditions for clinical examination however; clinical circumstances that necessitated emergency procedure without a signed Consent should be documented later on in the patient's record by the most responsible physician/attending physician or physician designee
- Consent for non-invasive or routine procedures shall be taken as 'implied' for example, where the patient allows the doctor to draw a blood sample for lab tests
- Consent is required for the sharing/receiving Confidential Health Information (CHI) with/from an Authorised Health Insurance Company/Health care Provider. Reasons for this include to:
    - Share/receive Confidential Health Information (CHI) with/from an authorised Health Insurance Company/Health care Provider
    - Grant the Authorised Health Insurance Company the right to audit the electronic medical records/related information, such as billing

<u>Consent for Hospital Admission and Treatment in a Hospital or Day Surgery Setting</u>

- A Consent Form should be given to the Patient and/or Substitute Consent Giver upon presentation to the appropriate admissions area
- Consent will cover normal medical interventions such as administration of medication, assessment and examination of appropriate non-invasive procedures considered routine in the provision of care

5. SPECIAL HEALTH CARE SERVICES AND INTERVENTIONS THAT REQUIRE CONSENT

Patient Transportation

- When an inpatient is waiting to be transported to, or participate in, activities outside the Health care facility
- When an inpatient is to be transported by persons other than the Parent or Substitute Consent Giver during the day and/or for overnight stay
- When the inpatient is a minor or is not competent to give Consent, The Substitute Consent giver shall be sought
    - The Consent from The Substitute Consent giver should include the names, addresses, relationships and telephone numbers of such persons

Serological Testing

- Implied Consent suffices for health care screening services and serological testing such as HIV, Hepatitis B, Hepatitis C and THLC
    - Serological tests for visa screening are mandatory by Law in the UAE
- As per UAE Law the Physician has the duty to report to the appropriate Authorities
- Where refusal of testing may lead to a Public Health threat/concern

Tele-Medicine

- Verbal, electronic or written Consent should be obtained voluntarily from the patient or Substitute Consent Giver before beginning the use of tele-medicine services for example, tele-consultation. In cases this should be noted in the patient's record
- The patient or Substitute Consent Giver should be made aware where recording devices are used and that the release of such recording data shall require written patient authorisation
- The participation and identity of the patient and/or Substitute Consent Giver should be confirmed prior to consultation and documented in the patient records;
- The physician and/or health care professional should verify:
    - The identity of the person giving Consent
    - The patient on whom the intervention is to be performed
    - The planned intervention and/or treatment
    - That the Consent giver and/or Substitute Consent Giver acknowledges that adequate information about the procedure and
    - alternatives have been given
    - That the Consent giver and/or Substitute Consent Giver gives the Consent voluntarily

Human Subject Research

No investigator and/or researcher should involve a human being as a subject in research before obtaining Informed Consent from either the subject or the Substitute Consent Giver and approval from the authorised or designated ethics committee.

6. CONSENT TAKER

- Consent applies to all physician and allied health care professionals providing treatment/ procedures, screening and prevention programmes and all entities involved in research involving human subjects
- In general, the most responsible physician and/or his or her physician designee is responsible for obtaining the appropriate Informed Consent before patient transportation or a surgical, dental, diagnostic, or invasive procedure.
- Emergency Room (E.R.) and emergency service providers/staff are not required to obtain Consent when treating emergency case.
- Hospital admissions, day surgery centres, primary care, clinics and centres are required to obtain the appropriate Consent in line with best practice
- Where research is being undertaken, it is usually the responsibility of the principle research investigator to obtain Informed Consent consistent with the HAAD Policies (Appendix A)

Recording and Reviewing Decisions

- The physician and/or allied health care professional should make use of the patient's medical records or Consent form to record the key elements of the decision made with the patient. This should include any specified patient requests, visual, audio or written material provided to the patient and any decisions that were made:
- The physician and/or health care professional should ensure that decisions made are reviewed with the patient and/or Substitute Consent Giver prior to the procedure, intervention or treatment to ensure that the patient and/or Substitute Consent Giver still wishes to continue
- The physician should respond to any new or repeated concerns where:
    - Significant time has passed since the initial decision was made. Significant time should be proportional to the treatment, evidence based and physician and/or health care professional decision
    - There have been material changes in the patient's condition, investigation or treatment
    - New information has become available on the risks of treatment, the treatment options and treatment outcomes
- The physician and/or health care professional shall ensure the patient is kept informed on the progress regarding their treatment, and ensure patients are able to make continued decisions about their procedure, intervention or treatment

7. CONSENTGIVER

Patient
Consent can be signed directly by the patient if the patient is *18 years of age or older*, unless there is evidence to verify incompetence regarding the decision to be made.

Substitute Consent Giver
Situations requiring a Substitute Consent Giver:

- When the patient is less than18 years of age
- Deemed incompetent
- In accordance with the Law and cultural tradition *only* procedures involving reproductivity and fertilisation in a female patient require Consent to be obtained from the patient and the husband and/or Substitute Consent Giver regardless of their age
- When the patient is deemed incompetent

Legal Guardian
A legal guardian may give Consent for a minor under his/her guardianship. This may include cases where the child lives with grandparents or other family members who have legal guardianship status by authorised competent Court of Law. An authorised competent Court of Law is one that has jurisdiction in the child's country where the decision was approved

Zayed High Organisation for Humanitarian Services in Abu Dhabi or its delegate or successor (or equivalent entities in UAE, if applicable) is the proper authorised entity to give Consent if the child resides in a permanent ward/home

8. DETERMINIATION OF INCOMPETENCY & INCAPACITY STATUS FOR CONSENTPURPOSES

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

Competency (Decision Making Ability)

- It should be assumed that all patients are competent to give an authorisation for treatment in the absence of reliable evidence to the contrary
- The competency of any patient, when doubted, should be decided on whether the patient is or is not capable of understanding the nature and consequences of a procedure, intervention or treatment decision
- A physician or health care professional who doubts the capacity of a patient to make a treatment decision should assess the patient's situation and document their professional judgment. If the assessment raises doubt about the patient's

capacity to make a decision on their treatment, then the physician and/or health care professional should seek advice from:
    - Nursing staff or other health care professionals involved in the patient's care;
    - Colleagues with relevant specialist experience and expertise such as psychiatrists, neurologists, or speech language therapists
- A patient is deemed to be incompetent if he/she is unable to understand the risks and benefits of the proposed treatments, is unconscious, or is in a health condition where it does not permit them to give Consent and/or one of the critical elements of a valid Consent were absent. In such circumstances, a Substitute Consent Giver should be sought to Consent for the Incompetent Patient

Capacity to Make Treatment Decisions

A patient is generally deemed incapable of making treatment decision in the following situations:

- If the patient that is not of full capacity i.e. if he/she is incapacitated or under age
- If the patient has been pre-medicated (with analgesic, sedative or other drugs that may alter their ability to understand or make decisions) they should be assessed by a physician and/or health care professional, regarding their capacity to make a rational decision and to give valid Consent
- If the patient is of full capacity but his/her Consent cannot be obtained for the following reasons:
    - Unconsciousness
    - Lack of discernment due to mental or psychiatric illness
    - The patient's health condition does not permit it

9. ELEMENTS THAT VALIDATE CONSENTFOR HEALTH CARE SERVICES AND INTERVENTIONS

Specificity

- The Consent authorisation should be specific for the procedure to be performed and should include the nature of the specific procedure, sub-procedure and variations of the procedure
- A physician and/or health care professional should not exceed the scope of the Consent and engage in other interventions, except those interventions deemed to be necessary in the course of the intervention or treatment
- The physician and/or health care professional should not seek Consent for a procedure, intervention or treatment that is out of his/her scope of practice, expertise, knowledge and/or privileges
- Alterations on a completed Consent form should be made before the intervention commences and the alterations should be signed and dated by the Consent giver, physician and/or health care professional. Notation of the alteration and the

reason for it should be made in the patient's health record

- Forms, Information brochures/pamphlets/media as appropriate, ink pens, and an interpreter can be utilised as appropriate. Also, at times a Patient Relations Officer and/or Health Care Facility Legal Advisor opinion may be sought

Voluntariness

- Consent should be free of undue influence, coercion or stress
- Pertinent information should be presented in a way that allows the Consent giver to reach an independent and reasoned decision about their care
- The physician or allied health care professional should listen to patient concerns, encourage patient participation and answer questions honestly
- The physician or allied health care professional should check the patient has understood the information that has been provided and ask whether or not further information is required to make a decision
- Patients have the right to revoke their Consent prior to treatment and the physician or allied health care professional should make it clear to the patient that they can change their mind about their decision at any time prior to the commencement of their procedure, intervention or treatment

Accuracy

- The Consent obtained should be accurate and free of misrepresentation of material concerning the proposed treatments
- Intentional withholding of information, well-intentioned exaggeration, distortion or trivialisation of material information invalidates the authorisation for Consent

Respect for Patients Decisions

- The physician and/or health care professional should respect a patient's decision to refuse an investigation or treatment, even in cases where the decision may not be rational
- The physician and/or health care professional should explain their concerns and outline the consequences of the patient's decision
- In cases where a life or limb saving procedure is refused, it is recommended for the physician and/or health care professional to document this occurrence in the 'Against Medical Advice' (AMA) form or in the appropriate section of the Consent form)
- The physician and/or health care professional should not put any undue pressure or stress on the patient if the patient offers a different point of view, requires more information or time to come to a decision(s) or decides to opt of treatment

Opportunity for Questions and Answers

The Consent process is contingent on good communication

- All reasonable steps should be taken to open and sustain good communication and to avoid rushing the Consent process
- Patients should have the opportunity to ask questions and have them answered in an understandable manner
- Patients should be given time to understand the information and to consult with others, if they choose to, before making a decision
- Clear and concise information should be provided in a language and vocabulary that is understandable to the Consent giver. Communication difficulties may be overcome through the use of competent translators and/or appropriate technologies

Information on the Intervention

- The health care professional should inform the patient and /or Substitute Consent Giver of details of the intervention. Such information should include why the procedure is needed and what it is supposed to accomplish.
- The physician should also identify any adverse outcomes that may occur from proposed treatment options including:
    - Risks for taking action
    - Side effects
    - Complications
    - Failure of an intervention to achieve the desired outcome; and
    - Risks that may be compounded as a result of the patient's history.
- In deciding how much information to share with a patient, the physician should take into account the patient's needs. The information provided should be proportionate to the:
    - Patient's condition
    - Complexity of the proposed procedure, intervention or treatment; and
    - Seriousness of any potential side effects, complications or other risks.
- Additional complementary information to the patient may be provided directly through teaching through videos, literature and other means to help educate patients. Any such information provided should be documented in the patient record

Reasonable Alternatives

- It is recommended that the treating physician and/or health care professional disclose information on treatment alternatives' existence and availability, if any. There should also be an explanation of the expected immediate short-term and long- term impacts on the patient's lifestyle including on the patient's employment, social or personal life

Witnessing Consent

- Informed Consent shall be witnessed. A witness shall be present during the discussion and signing of the procedure and where necessary include a translator if there are language barriers between any of the parties involved.

- The witness of written Consent should be someone other than the primary operator for the intervention. The translator can act as the witness, if necessary.
- The patient shall be asked to sign his/her legal name in the appropriate section of the Consent form or electronic Consent form. Thumb print may be used instead of patient signature if the patient is unable to write their signature
- If the patient is unable to sign, the Substitute Consent Giver can sign and indicate his/her relationship to the patient. The physician and/or health care professional should witness the signature and this should be supported with documentation to verify that they are the Substitute Consent Giver
- It is good practice to have a Patient Relations Officer informed and document the fact that all attempts were made to contact a Substitute Consent Giver

Telemedicine Services

- The participation and identity of physician and/or health care professional should be explained to the patient or Substitute Consent Giver
- The patient should be made aware and approval should be granted by patient the or Substitute Consent Giver of any other people present prior to their tele-consultation, intervention or treatment
- The patient or Substitute Consent Giver should be made aware and approval should be granted prior to the intervention or treatment, if a third remote site is participating in the tele-consultation
- Patient data may not be viewed by other remote networked location without the patients or Substitute Consent Giver's Consent
- Patient photographs, audit recording or video recording should not be used without the patient's or Substitute Consent Giver Consent
- Documentation and completion of Consent for the Tele-medicine intervention should include the name of the person providing the information to the Consent Giver, and their relationship to the patient. Date, time and summary of the information given should also be documented and the information provided in order to obtain Consent (with limitations, if any)

Human Subject Research

It is recommended that a valid Informed Consent form for research include the following elements:

- Details of 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
- Treatment(s) included in the research and the probability of random assignment to each treatment
- Description of any foreseeable risks and benefits to the subject
- Explanation of compensation and/or medical treatments available if injury occurs to the subject

- Anticipated circumstances under which the subject's participation maybe terminated by the investigator without regard to the subject's Consent
- Disclosure of any appropriate alternative procedures or courses of treatment
- Subject's responsibilities with respect to the research
- Description of how confidentiality will be maintained
- A statement addressing direct access to the subject's medical records by the Facility Research Ethics Committee (REC), auditors, Abu Dhabi Health Research Council and/or agents of each, for the verification of the procedures and/or data associated 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
- Consequences of a subject's decision to withdraw from the clinical research and procedures for orderly termination of participation by the subject
- A statement addressing cultural and religious concerns/indications, if applicable
- Any additional costs to the subject that may result from participation in the clinical research
- A statement that significant new findings developed during the course of the clinical investigation and that may relate to the subject's willingness to continue participation will be provided to the subject

- Additional elements are usually required for obtaining and documenting Informed Consent from specific groups of individuals, that include but are not limited to:
    - Individuals with impaired mental capacity
    - Children
    - Non-English speaking subjects and
    - Illiterate subjects

10. INFORMATION ON WHO WILL PERFORM THE PROCEDURE

- The physician and/or health care professional should ensure the patient is informed of the likelihood that performing the procedure may involve a number of qualified health care professionals
- The information should include but is not limited to: providing information where trainees may be involved such as interns, medical trainees, residents and/or other health care students who may participate in interventions under the supervision of a fully qualified and HAAD licensed physician and/or health care professionals
- The physician and/or health care professional undertaking the treatment or intervention should discuss the procedure with the patient
- Where this is not practical, then the physician and/or health care professional should have a governance arrangements and an supporting policy that enables the delegation of this responsibility to someone who:

- Is licensed by HAAD
- Is suitably trained and qualified
- Has sufficient knowledge of the proposed investigation, procedure, intervention or treatment
- Understands the risks involved
- Understands, and agrees to act in accordance with their policy
- Is privileged by the health care facility to perform such task

- Where delegation occurs this should be recorded in the patients notes
- The delegating physician and the physician providing the intervention or treatment is usually responsible to ensure the proper Consent is met and are familiar with the patient's medical history

11. DURATION AND VALIDITY OF CONSENT

- The most responsible physician and/or health care professional is generally responsible for ensuring that the Consent remains valid from the time of Consent is given to the commencement of the treatment, intervention or investigation unless:
  - It is withdrawn by the patient and/or Substitute Consent Giver
  - A change is made in the planned and Consented intervention
  - An assessment indicates the patient's condition has changed and requires a new treatment plan
  - The Consent is invalidated by one of the above, the Consent should be renewed and verified by signature and date from the most responsible physician and Consent Giver
- Certain conditions may require frequent treatment and therefore may lead to agreement between the health care professional and the patient and/or Substitute Consent Giver on the duration of the Consent. Examples of such cases include but are not limited to:
  - Consent for Blood Components
  - Consent for Dialysis
  - Circumstances that necessitate emergency transfusion of blood products without a signed Consent shall be documented in the patient's medical record

<u>Change or Extension from the Specific Treatment</u>

When the physician and/or health care professional 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 should be disclosed to the patient and/or Consent giver and Consent should be obtained and the change of procedure should be recorded in the patient record

12. REFUSAL OF TREATMENT

When the Patient is a Competent Adult

- The physician and/or health care professional should ensure that the patient understands and knows the nature and consequences of refusal to submit to tests or treatment including the problems to be encountered by refusing treatment
- A patient should be fully informed about the various treatments and procedures that are necessary by the most responsible physician(s) and/or health care professionals and understands the risks and benefits of the proposed treatments
- Where intervention or treatment is refused or when a patient self-discharges, the physician and/or health care professional should take all reasonable steps/attempts to inform the patient of the risks involved in refusal
- Once fully informed, a patient may choose among different treatment alternatives or may refuse all forms of treatment
- A competent adult has the right to refuse any treatment or intervention, even though such refusal may endanger his/her life or health
- In cases where a life or limb saving procedure is refused, it is recommended for the physician and/or health care professional to document this occurrence in the 'Against Medical Advice' (AMA) form or in the appropriate section of the Consent form)
    - It is recommended for patients to sign the appropriate section/form and for this to be witnessed by another member of staff and kept in the patient record
- If the patient asks for treatment that the physician and/or health care professional considers would not be of benefit to the patient, then it is recommended that they discuss this and explore the reasons behind the request
- If the patient insists on the treatment that is deemed by the physician and/or health care professional to have no benefit or cause harm, then the physician or health care professional may refuse to provide treatment and explain their reasoning. In such cases, the physician and/or health care professional have a duty to offer alternative treatment options including referral for a second opinion

When the Patient is a Minor or an Incompetent Adult

- The Substitute Consent Giver for a patient should be given full information on the various treatments/tests/procedures that are necessary, including their risks and benefits
- A Substitute Consent Giver has the right to refuse the proposed treatments/tests/procedures
- In the event that the Substitute Consent Giver refuses an intervention for a minor in a Life Threatening Case, it is recommended for the physician and/or health care

professional to document this occurrence in the 'Against Medical Advice' (AMA) form or in the appropriate section of the Consent form (see section 4)

- In general, the decision of the Substitute Care Giver prevails and is relied on by the physician and/or in situations where one relative Consents to an intervention, and another refuses it

13. LEGAL ADVICE

Legal advice can be sought where questions remain in regards to the patient's capacity to make a decision about their procedure, intervention or treatment. In such cases, the following should be considered:

- If there is a Substitute Consent Giver
- If the lack of capacity is temporary or specific to the nature of the procedure, intervention or treatment
- Which treatment option has minimal risk
- The option not to treat and its advantages and disadvantages
- The least restrictive of the patient's future choice
- Any evidence of previous patient requests
- Supporting evidence to support the physicians concerns

APPENDIX

APPENDIX A – LAWS, REGULATIONS AND POLICIES RELATED TO THIS GUIDELINE

1. Federal Law No. (7) of 1975. Concerning The Practice of Human Medicine. Articles, 12-26.

2. Federal Law No. (10) of 2008 Concerning Medical Liability. Articles, 3-14.

3. Cabinet Decision No. (33) of 2009. Issuing the Implementing Regulation of Federal Law No. (10) of 2008 Concerning Medical Liability. Articles, 2-12.

4. Federal Law No. (15) of 1993. Regulating the Transfer and Transplant of Human Organs. Articles 2-7.

5. Ministerial Decision No. (566) of 2010 on the implementing Regulation of Federal Law No. (15) of 1993 Regulating the Transfer and Transplant of Human Organs. Articles, 2-8.

6. Health Ministers Council for GCC States Decision No. (3) dated 26/04//1427 corresponding to 14/05/2006. Articles, 3-6 and 8.

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APPENDIX B - DUTIES OF PHYSICIANS, ALLIED HEALTH CARE PROFESSIONALS AND HEALTH CARE PROVIDERS

1 Knowledge, skills and performance

1.1 Make the care of your patient your first concern;
1.2 Provide a good standard of practice and care;
1.3 Keep your professional knowledge and skills up to date; and
1.4 Recognise and work within the limits of your competence and where
1.5 appropriate involve other health care team members in discussion with the patient.

2 Safety and quality

2.1 Take prompt action if patient safety, dignity or comfort is being compromised; and
2.2 Protect and promote the health of patients and the public.

3 Communication, partnership and teamwork

3.1 Treat patients as individuals and respect their dignity;
3.2 Treat patients politely, considerately and sensitively;
3.3 Respect patients' right to confidentiality;
3.4 Work in partnership with patients;
3.5 Give patients the information they want or need in a way that they can understand to make informed decisions;
3.5.1 Information may be provided using written information, visual or other aids and the physician shall ensure this information is accurate and up to date and documented in the patient record.
3.5.2 However, it is not intended to replace the information exchange between the health care professionals and the Consent Giver. Any such interaction should be documented in the patient's record.
3.6 Ensure the patient understands where there is a time limit to making a decision about their investigation or treatment;
3.7 Ensure the patient is given adequate time to reflect on the information provided, especially in complex cases or cases that involve significant risks and may require the patient to consultant with either another physician, parent, relative, husband or wife or friend.
3.8 Listen to, and respond to, the patients concerns and preferences.
3.9 Listen to Patients and Respect patients' right to reach decisions with you about their treatment and care;
3.10 Support patients in caring for themselves to improve and maintain their health; and
3.11 Work with colleagues in ways that best serve patients' interests.

4 Maintaining Trust

4.1 Be honest and open and act with compassion and integrity;
4.2 Never discriminate unfairly against patients or colleagues;
4.3 Never abuse patients' trust in you or the public's trust in the profession; and
4.4 Professionals are accountable for their professional practice and must always be prepared to justify decisions and actions taken.

5 Assumptions

5.1 The health care professional should not make assumptions about:
- 5.1.1 the information the patient might want or need;
- 5.1.2 the clinical or other factors a patient might consider significant;
- 5.1.3 a patient's level of knowledge or understanding of what is being proposed and the nature of their condition;
- 5.1.4 the patient's needs, wishes or priorities;
- 5.1.5 the patients understanding of the nature and level of risk associated with the investigation or treatment; and
- 5.1.6 the patient prognosis and outcomes

6 Consent Related-Reasons not to share information

6.1 The health care professional should explore any cases where the patients (or authorised Substitute Consent Giver) does not want information about their investigation or treatment. If after discussion the patient does not want any detail about their condition or treatment, the physician should respect the patient's wishes as far as possible but provide sufficient information to the patient in order to obtain Consent;

6.2 Where the patient insists that they do not want the basic information, the physician should explain the potential consequences of not having the necessary information and if Consent is deemed invalid. The physician should record this in the patient notes and advise the patient that they may seek further information at any time.

6.3 The health care professional should not withhold necessary information for a patient (or authorised Substitute Consent Giver) to make a decision about their care unless he/she believes it would cause serious harm to the patient.

6.3.1 Where information is withheld this should be documented in the patients record and the physician must be prepared to justify this decision.

6.4 The health care professional should regularly review the patients record and consider when it would be appropriate to share the information where serious harm would not occur.

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