

GUIDELINES FOR PATIENT CONSENT



Health Policies and Standards Department

Health Regulation Sector (2019)

INTRODUCTION

Health Regulation Sector (HRS) forms an integral part of Dubai Health Authority (DHA) and is mandated by DHA Law No. (6) of 2018, to undertake several functions including, but not limited to:

- Developing regulation, policy, standards, guidelines to improve quality and patient safety and promote the growth and development of the health sector
- Licensure and inspection of health facilities as well as healthcare professionals and ensuring compliance to best practice
- Managing patient complaints and assuring patient and physician rights are upheld
- Managing health advertisement and marketing of healthcare products
- Governing the use of narcotics, controlled and semi-controlled medications
- Strengthening health tourism and assuring ongoing growth
- Assuring management of health informatics, e-health and promoting innovation

The Guidelines for Patient Consent aims to fulfil the following overarching DHA Strategic Objectives and Program within the Dubai Health Strategy (2016–2021):

- Objective 1: Position Dubai as a global medical destination by introducing a value-based, comprehensive, integrated and high-quality service delivery system
- Objective 2: Direct resources to ensure happy, healthy and safe environment for Dubai population
- Strategic Program 10: Excellence & Quality, which promotes excellence in healthcare service delivery in Dubai while enhancing patient happiness, experience, satisfaction and trust

ACKNOWLEDGMENT

The Health Policy and Standards Department (HPSD) developed this Standard in collaboration with Subject Matter Experts. HRS would like to acknowledge and thank these professionals for their dedication toward improving quality and safety of healthcare services.

Health Regulation Sector

Dubai Health Authority

TABLE OF CONTENTS

INTRODUCTION	2
ACKNOWLEDGMENT	3
EXECUTIVE SUMMARY	5
DEFINITIONS	6
ABBREVIATIONS	8
1. BACKGROUND	9
2. SCOPE	9
3. PURPOSE	9
4. APPLICABILITY	10
5. RECOMMENDATION ONE: OBTAINING INFORMED CONSENT	10
6. RECOMMENDATION TWO: SEQUENCE OF PRIORITY	14
7. RECOMMENDATION THREE: CONTENT OF THE INFORMED CONSENT	15
8. RECOMMENDATION FOUR: VALIDITY OF THE CONSENT	17
9. RECOMMENDATION FIVE: DOCUMENTATION OF THE CONSENT	18
REFERENCES	19
APPENDICES	21
APPENDIX 1: EXAMPLES OF PROCEDURES THAT REQUIRE CONSENT	21
APPENDIX 2: MINIMUM REQUIREMENTS FOR INFORMED CONSENT FORM	23

EXECUTIVE SUMMARY

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 healthcare 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 healthcare professionals should always respect the patient's right to make decisions about their care.

A number of UAE Federal and DHA Laws, Decrees and Policies govern Informed Consent in Healthcare. This document serves as a guideline for physicians and Allied healthcare professionals to implement the Consent as per DHA Regulation and UAE Laws and sets out best practice for physicians and allied healthcare professionals to obtain Informed Consent before the following main scenarios:

- Undertaking any examination or investigation
- Providing interventions or treatment
- Telehealth services

This guideline sets out to encourage the adoption of best practices for patient consent. This guideline is not obligatory nor exhaustive therefore, health facilities are encouraged to determine the best approach for managing patient consent in their own setting with the provision that they are aligned to best practices and the UAE Laws and local regulations. This document also sets out the importance of documenting and educating healthcare professionals regarding the Informed Consent.

DEFINITIONS

Competent refers to every adult person, 18 years and above as presumed to be capable of and competent to give an informed consent, unless there is an evidence to verify incompetence

Consent is a declaration of a person's willingness and choice 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.

Cooling off period: The point from when a patient has a pre-op assessment to the day of surgery.

Physician shall mean DHA licensed physician or dentist

Electronic signature refers to any letters, numbers, symbols, voice or processing system in electronic form applied to, incorporated in, or logically associated with a data message with the intention of authenticating or approving the same

Emergency shall mean a situation that requires an immediate surgical intervention to preserve the patient's life or prevent major complications.

Healthcare professional shall mean a natural person who is authorized and licensed by the Dubai Health Authority to practice any of healthcare professions in the Emirate.

Healthcare worker shall means an individual employed by the health facility, (whether directly, by contract with another entity), provide direct or indirect patient care, this includes but not

limited, healthcare professionals, medical and nursing students, administrative staff and contract employees who either work at or come to the hospital site

Incompetent patient refer to the patient who either lack the full legal capacity or have the full capacity, but unable to provide an Informed Consent.

Informed Consent refers to an agreement or permission accompanied by full information on the nature, risks and alternatives of a surgical or interventional procedure before the physician begins the procedure/treatment. Accordingly, the patient either consents to or refuses treatment.

Legal guardian shall mean a person appointed by the law to consent in place of an incompetent patient based on UAE federal laws and/ or local regulation, when the patient is unable to provide Informed Consent due to an illness or incompetency.

Medical negligence is substandard care that has been provided by a healthcare professional to a patient, which has directly caused injury or caused an existing condition to get worse. There's a number of ways that medical negligence can happen such as misdiagnosis, incorrect treatment or surgical mistakes.

Minor refers to any person below eighteen (18) years of age

Next of kin refers to a person who is authorized to make decision on behalf of the patient (In case the patient is incompetent). Next of kin may include relatives up to the forth degree. In case relatives up to the forth degree are not available, then relatives available from the same origin of the spouse's side will be considered as a next of kin

Procedures are surgical interventions, which requires obtaining Informed Consent from the patients or next of kin/ legal guardian, as per UAE federal laws

Relatives up to the forth degree refers to the following sequence of relatives: father/mother/husband/wife/son/daughter/grandfather/grandmother/grandsons/granddaughters/father's brother/father's sister/mother's brother/mother's sister/sons of the father's brother/sons of the father's sister/sons of the mother's brother/sons of the mother's sister

Treatments are those cases of special nature that are defined by the executive council regulation affiliated by the federal law. This include treatments of chemotherapy, radiation therapy and endoscopies.

ABBREVIATIONS

CBD	:	Community Based Physician
DHA	:	Dubai Health Authority
HRS	:	Health Regulation Sector
TCAM	:	Traditional, Complementary and Alternative Medicine
UAE	:	United Arab Emirates

1. BACKGROUND

Dubai Health Authority (DHA) is pleased to present the Guidelines for Informed Consent, which represents a milestone towards fulfilling the DHA strategic objectives to improve quality standards in health facilities. This document provides guidance to health facilities and healthcare professional to ensure that the process of obtaining and documenting consent is managed appropriately, and in line with the United Arab Emirates (UAE) jurisdictional and legislative requirements. Consent is an agreement between healthcare professionals and patients to provide specific treatment. There are three types of consents:

- **Written consent** (Informed Consent) is when, the patient signs the consent to confirm the agreement to a specific procedure/treatment, due to a significant risk.
- **Verbal consent** is where, the patient orally state the agreement to a procedure/treatment, which does not carry a significant risk.
- **Implied consent** is where, the patient indicates their agreement through actions or by cooperating with the healthcare professional instructions. For example, blood tests.

2. SCOPE

2.1. To assure provision of the highest levels of transparency, safety and quality of healthcare services in DHA licensed health facilities.

3. PURPOSE

3.1. To support the adoption of Informed Consent among DHA licensed health facilities with emphasises on the responsibility of healthcare professional's accountability to

provide adequate information to patients, in order to make an informed decision and to identify the sequence of priority for obtaining Informed Consent in case the patient is incompetent.

4. APPLICABILITY

4.1. To all DHA licensed health facilities and healthcare professional providing healthcare services in the Emirate of Dubai.

5. RECOMMENDATION ONE: OBTAINING INFORMED CONSENT

5.1. Different types of written consents should be obtained from the patient based on the type of procedures/treatments which include, but not limited to:

5.1.1. Pre-op Assessment.

5.1.2. Surgical or invasive procedures.

5.1.3. Anaesthesia.

5.1.4. Use of blood and blood products.

5.1.5. Chemotherapy and radiation therapy.

5.1.6. Interventional procedures such as endoscopy, or any other high-risk procedures/treatments.

5.1.7. Use of telehealth services.

5.1.8. Informed Consent in case students are involved in any form of patient care.

5.2. Where elective surgery is undertaken and requires pre-op assessment, consent shall be obtained at pre-op assessment and on the day of surgery. The period between the two consents is considered the cooling off period.

- 5.3. The health facility should identify a list of procedures/treatments that requires obtaining specific Informed Consent from patients. Refer to **Appendix 1** for an example of procedures/treatments that require a consent.
- 5.4. Ensure that the consent policy is accessible to all relevant healthcare professionals.
- 5.5. Orient and educate all healthcare professionals and concerned healthcare workers on the consent policy and procedures.
- 5.6. As per the UAE federal laws and DHA regulations, the health facility shall provide patients with information that will enable them to participate in making informed decision regarding procedures/treatments.
- 5.7. As per the Federal Decree Law No. (4) Of 2016, Concerning Medical Liability, Article 5, Informed Consent may not be mandatory in the following conditions:
 - 5.7.1. Immediate medical intervention is required, where consent cannot be obtained for any reason whatsoever. However, the clinical circumstances and other relevant reasons for not taking the Informed consent must be recorded.
 - 5.7.2. Where the patient has a contagious disease, which represents a threat to public health and safety.
- 5.8. However, as for examination, diagnosis and administration of the first dose of medication, consent of incapacitated patient is considered, if the patient's relatives or legal guardian is informed of the plan for such medication.

- 5.9. The treating Physician/Dentist or any treating healthcare professional e.g. physiotherapist or Traditional, Complementary and Alternative Medicine (TCAM) is responsible for taking the Informed Consent and documenting it.
- 5.10. Prior to providing Informed Consent, the treating physician should discuss with the patient the proposed procedure/treatment details, including but not limited to:
- 5.10.1. The patient's condition and diagnosis
 - 5.10.2. The proposed procedures/treatments and aftercare requirements
 - 5.10.3. The status of procedures/treatments (Approved, experiment, etc.)
 - 5.10.4. Potential benefits, side effects and risks
 - 5.10.5. Recovery and expected outcome
 - 5.10.6. Alternative options for the procedures/treatments (when applicable)
 - 5.10.7. The name of the treating physician/team.
- 5.11. All costs related to the procedures/treatments must be disclosed in writing by the responsible staff to the patient or his/her legal guardian.
- 5.12. The health facility must ensure written consent is document in the patient health records. A copy of the Informed Consent may be issued to the patient.
- 5.13. Sufficient time shall be given to the patient to read and understand the Informed Consent before commencing the proposed procedure/treatment to make an informed decision.
- 5.14. If the treating physician is a Community Based Physician (CBD) having a part time license and is privileged to provide specific procedures/treatments in a hospital or a

Day Surgical Centre, it is the responsibility of the treating physician to obtain the Informed Consent before commencing with the procedure/treatment. In such cases, a copy of the signed Informed Consent should be communicated and documented in the patient's health record in the health facility providing the procedure/treatment.

5.15. The health facility should make every effort to ensure the understanding of the Informed Consent by patient. The following approaches maybe useful:

5.15.1. Use of diagrams and models for description of the procedure/treatment.

5.15.2. Ask patient to repeat what they have been told to measure their understanding.

5.15.3. If needed, have an interpreter to assist in translation who should also sign the Informed Consent.

5.16. The patient shall be capable of fully understanding the information given to him/her about the procedures/treatments and decide whether or not to proceed with it.

5.17. If the treating physician has determined that the patient is not competent to provide an Informed Consent, it shall be clearly documented in the patient health record.

5.18. The information provided shall be in a non-technical language, which is easily understood by the patient.

5.19. The patient shall be provided with accurate answers in response to questions raised regarding the procedure/treatment.

5.20. The patient reserves the right to refuse treatment.

5.21. If the patient refuses the proposed procedure/treatment, the treating physician shall document the patient refusal and information regarding the consequences of refusal.

6. RECOMMENDATION TWO: SEQUENCE OF PRIORITY

- 6.1. A competent adult is presumed to be capable of giving consent, unless proved otherwise.
- 6.2. Married female may sign her own Informed Consent except procedures/treatments related to reproductive health where the husband (first priority) or the legal guardian's consent is mandatory.
- 6.3. Informed Consent from next of kin can be taken in the following cases:
 - 6.3.1. Incompetent patient
 - 6.3.2. Minor
- 6.4. In case the patient is incompetent or unable to give the consent, the priority of obtaining the consent from the next of kin should be from the relatives up to the fourth degree, as mentioned below:
 - 6.4.1. If the patient is married female, the husband consent is prior to the father.
 - 6.4.2. The mother can consent for her children in emergency cases when the father is not present.
 - 6.4.3. For minor of divorced parents, the parent who has the custody is the appropriate person to give consent. However, the other parent has the right to receive information regarding the child's medical condition and/or procedure/treatment.
 - 6.4.4. If the patient does not have any relative available in the country, the legal guardian/sponsor can be the next of kin.

6.4.5. For patients who are 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 dependant.

6.5. When a patient is a minor or incompetent, and there is no next of kin to be involved despite of taking all measures to contact a next of kin, then the authorization to be signed by the most responsible physician for the procedures/treatments of the patient and to be witnessed by another healthcare professional.

7. RECOMMENDATION THREE: CONTENT OF THE INFORMED CONSENT

- 7.1. The health facility shall develop a specific Informed Consent form for every procedures/treatments.
- 7.2. Forms shall be in Arabic, English or other language based on community needs.
- 7.3. The completed form becomes part of the patient's health record.
- 7.4. For elective procedures, Informed Consent should be obtained in a suitable environment with adequate time to discuss details of the procedure.
- 7.5. If the patient under the influence of analgesics, sedatives or other drugs that may alter his/her ability to understand or make decisions, he/she must be assessed regarding his/her capacity to make a rational decision and to give valid consent, if not the Informed Consent should be obtained from the next of kin.
- 7.6. If it is established that the patient was not fully alert due to the above reasons during the Informed Consent then the consent may be deemed invalid.

- 7.7. The patient or next of kin 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/she can comprehend, and to have any relevant questions answered.
- 7.8. Patients are not liable to pay for any medical negligence, hospital acquired infections, malpractice, duplications in management by the health facility staff. These should be covered by the Health facility's malpractice insurance.
- 7.9. The content of the Informed Consent should include but not limited to the following and also refer to **Appendix 2**.
- 7.9.1. Patient full name as per the passport/Emirates ID, age, gender and patient identification number.
- 7.9.2. Name of the proposed procedure/treatment.
- 7.9.3. Name, date, time and signature of the treating physician
- 7.9.4. Name and signature of the witness or interpreter.
- 7.9.5. Statement that the treating physician shall be discussed with the patient in understandable method the procedure/treatment, expected outcomes, relevant risks, complications, side effects and alternative treatment options.
- 7.9.6. Statement regarding all procedures/treatments that are not covered by insurance or which may require the patient full payment or co-payment.
- 7.9.7. X-ray of pregnant or possibly pregnant woman when the use of safety precautions such as lead shields, is not feasible and a risk exists to the pregnancy (i.e. abdominal x-ray).

7.9.8. Photography/Videography of patient's before/during/after procedures/ treatments and the use of these for marketing purposes (if applicable).

8. RECOMMENDATION FOUR: VALIDITY OF THE CONSENT

8.1. The health facility should identify the validity of the Informed Consent, which should meet the following:

Type of consent	Duration of consent
Informed Consent	<ul style="list-style-type: none"> Valid from the time signed by the patient or the next of kin/legal guardian to the time of the procedures/treatments is performed The validity should not exceed ninety (90) days from the date of signature, if the patient condition has not changed.
Anaesthesia	
Use of blood and blood products	<ul style="list-style-type: none"> Valid per episode of administering or order Patient who needs multiple transfusions the consent is valid up to one (1) year if there is no change in the patient's condition.
Chemotherapy	Valid for the whole course of treatment, unless there is a change in the plan of treatment due to altered blood chemistry.
Radiation Therapy	
Dialysis	

8.2. A consent is considered as invalid, in the following cases:

8.2.1. Informed Consent is withdrawn by the patient

8.2.2. Reassessment of the patient indicates that the patient's condition/diagnosis has changed

8.2.3. A change or modification is made on the consented procedure/treatment

8.3. If the consent is considered invalid, a new Informed Consent shall be obtained.

9. RECOMMENDATION FIVE: DOCUMENTATION OF THE CONSENT

9.1. The treating physician shall be responsible to ensure that the Informed Consent remains valid from the time of consent to the commencement of the procedure/treatment.

9.2. Informed Consent forms shall be completed and placed in patient health record. The retention period shall be as per the Managing Health Records Policy and DHA Guidelines for managing Health Records.

9.3. The use of abbreviations shall not be permitted when documenting on Informed Consent forms.

9.4. Electronic version of Informed Consent forms is an acceptable method for obtaining the patient's consent.

9.5. If the health facility is using electronic health records, electronic signature is acceptable.

9.6. The content of the electronic Informed Consent forms shall meet the same requirements as that of the manual consent mentioned in this document.

9.7. For storing and retrieving the Informed Consent form, the electronic health system shall maintain records of each entry with identified authentication.

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APPENDICIES

APPENDIX 1: EXAMPLES OF PROCEDURES THAT REQUIRE CONSENT

No.	Procedure
1.	All interventional cardiac/vascular procedures (diagnostic / therapeutic)
2.	All major and minor surgical procedures (diagnostic / therapeutic)
3.	All procedures under sedation and all types of anaesthesia
4.	All radiological studies requiring contrast
5.	All transfusions of blood and blood products
6.	Amniocentesis
7.	Argon or Yag laser for the eye
8.	Artificial insemination
9.	Bone marrow aspiration/trephine biopsy
10.	Bronchoscopy (diagnostic / therapeutic)
11.	Cardiac catheterization (diagnostic / therapeutic)
12.	Central venous catheterization (permanent / temporary)
13.	Chemotherapy
14.	Contrast echocardiogram
15.	Dacryosintigraphy
16.	Device implantation
17.	Elective cardioversion
18.	Electro-convulsive therapy

19.	Endoscopy and related procedures (diagnostic / therapeutic)
20.	Fluorescein fundus angiography
21.	Foley`s catheter insertion for new born
22.	Induction of labor (IOL)
23.	Insertion of inter-costal drainage tube
24.	Intermittent/continuous renal replacement therapy
25.	Intra uterine contraceptive device insertion/removal
26.	Intra-articular injection
27.	Intra-vertebral injection of medication
28.	Isotope studies
29.	Lumbar puncture/related therapeutic/diagnostic procedures
30.	Manometry and ph metry for upper gastrointestinal tract
31.	Pericardial aspiration
32.	Phototherapy
33.	Plasmapheresis

APPENDIX 2: MINIMUM REQUIREMENTS FOR INFORMED CONSENT FORM

Informed Consent Form For Patients
Name of Healthcare Professional: -----
Name of Health Facility: -----
Name of Patient: _____ File No: _____
This Informed Consent Form has two parts: <ul style="list-style-type: none">• Information Sheet (to share information about the treatment with you)• Certificate of Consent (for signatures if you agree to go ahead with the treatment)
<i>You will be given a copy of the full Informed Consent Form</i>
PART I: Information Sheet
Introduction:
I, Dr. _____ with license No: _____ should be performing the _____ treatment/ procedure on Miss/Mrs./Mr. _____ Aged _____ years, on date _____.
<u>Description of the Procedure and Process</u>
Describe to the patient or customer, the procedure and what will happen on a step-by-step basis. The patient should be informed that procedure is newly introduced and the amount of supporting research and study available.

Side Effects

Potential patients should be told if there are any known or anticipated side effects and what will happen in the event of a side effect or an unexpected event.

Risks

Explain and describe any possible or anticipated risks. Describe the level of care that will be available in the event that harm does occur, who will provide it, and who will pay for it.

Complications

Inform and explain any possible complications that could be caused as a result of the treatment.

Discomforts

Explain and describe the type and source of any anticipated discomforts that are in addition to the side effects and risks discussed above.

Benefits

Mention only those activities that will be actual benefits of the treatment.

Confidentiality

Explain how the clinical team will maintain the confidentiality of data, especially with respect to the information about the patient including photography and videography.

Right to Refuse treatment/procedure

This is a reconfirmation that the patient has the right to refuse the treatment.

Alternatives to clinical procedure or treatment

It is important to explain and describe the established standard treatment or procedure for the patient's condition.

Financial Implications

All procedures/treatments provided that are not covered by insurance or which may require the patient's full payment or co-payment.

PART II: Certificate of Consent

This section can be written in the first person. It should include a few brief statements about the treatment and be followed by a statement similar to the one in bold below. The healthcare professional performing the treatment and the person going over the informed consent should sign the consent.

Example:

Patient Consent statement

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to undergo tis treatment and understand that I have the right to withdraw from the procedure or treatment at any time without in any way affecting my medical care.

Name of Patient: _____

Signature of Patient: _____ **Date:** _____

Witness statement

I have accurately read or witnessed the accurate reading of the consent form to the potential patient, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Name of witness: _____

Signature of witness: _____ **Date:** _____

Healthcare Professional Declaration:

I have adequately explained to the patient about the procedure along with risks, adverse effects and the standard alternatives that are available for the procedure. I have permitted time and opportunity for the patient to ask questions and all questions have been answered to my knowledge

Name of healthcare professional: _____

Signature of healthcare professional : _____ **Date:** _____