INFORMED CONSENT

POLICY AND PROCEDURE

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POLICY AND PROCEDURE – Informed Consent

Introduction

Healthcare systems empowers patients' participation in decision making and considers patients as equal partners in healthcare decision making along with healthcare providers. Patients or those acting on their behalf must be provided with adequate information that will allow them to make an informed decision to agree to specific treatment and care. This process of providing an informed consent is more than signing off a written consent form. It is a process of communication between a patient and a healthcare professional that results in the patient's authorization or agreement to undergo a specific medical intervention.

The provision of relevant information has become synonymous with patients' rights and has long been a physician's ethical obligation. The informed consent process also covers legal aspects to protect both the patient and the healthcare professional from any undesired events resulting from a performed procedure. For non-emergency interventions, the information and the consent should be given in an environment where the patient has time to reflect over the given information, and is given opportunity to consult with others. In case of any conflict regarding information given, only written documentation is valid.

1. PURPOSE	
1.1	To ensure that no intervention is carried out without the patient's acceptance.
1.2	To support the DHCA Patient Charter on patients' rights.
1.3	To specify the essentials for valid consent.
1.4	To specify minimum requirements for obtaining and documenting informed consent.
1.5	To support decision making.
1.6	To enhance the continuity of patient care.
1.7	To improve patient care and treatment outcomes.
1.8	To diminish the risk of conflicting understanding between patients and/or their representatives on one hand, and healthcare professionals (HCPs) and healthcare operators (HCOs) on the other with respect to the content of the written informed consent.
1.9	To include consideration of situations where the patient is not capable of giving an informed consent.
1.10	To provide HCOs and HCPs with requirements and procedural guidelines in accordance with current regulations and standards to maintain an informed consent process that is functional and sustainable.

2. APPLICABLE TO	
2.1	This policy is applicable to all HCOs and HCPs in hospitals, outpatient clinics, and ambulatory surgery centers under Dubai Healthcare City Authority (DHCA) and its branches.
2.2	This policy does not address requirements for General Consent.
2.3	This policy does not include informed consent related to health related research on humans. HCOs and HCPs intending to perform such human subject research are required to obtain approval from the DHCR

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	Research Department and Research Ethics Committee in accordance with the DHCA Research Regulation No. 6 of 2013 and research policy titled as "Conducting Research in DHCC".

3. POLICY STATEMENTS

3.1	Consent is required for all interventions, procedures or treatments, as well as the use of telehealth services, photographs, and promotional activities except where authority is granted under appropriate legislation or a court order.
3.2	Each Healthcare Operator is to have an internal informed consent policy, supported by additional policies, procedures and processes as necessary, that is in compliance with: 3.2.1 UAE Federal Law No. (4) of 2016 Concerning Medical Liability and related legislation; 3.2.2 The minimum requirements for a written informed consent stated in this policy; 3.2.3 The DHCR Outpatient Clinic Quality Standards and/or the standards of the DHCR approved accreditation organization for hospitals; and 3.2.4 All other applicable rules, regulations and standards that are or may come in to effect.
3.3	Investigations, treatments, and procedures that require a written informed consent must be defined in the HCO's policy.
3.4	The process to follow if a patient refuses to provide consent for investigations, treatments, and procedures, must be defined.
3.5	All HCOs within DHCA are required to initiate, maintain, and secure a written consent in accordance with the requirements and procedural guidelines described in this policy for every patient who is to undergo any investigation, treatment, and/or procedure that requires a written informed consent.
3.6	It is the responsibility of the attending physician/HCP to obtain appropriate informed consent before any investigation, treatment, operation or other procedure as defined in policy.
3.7	It is the responsibility of the treating physician/HCP to ensure that valid informed consent has been given before commencing treatment.
3.8	It is the responsibility of the anesthesiologist or other qualified healthcare professional providing sedation or anesthesia to obtain written informed consent prior to administration of sedation or anesthesia.

4. PROCEDURE

4.1	**General Considerations** 4.1.1 Consent is required for all interventions, procedures or treatments except where authority is granted under appropriate legislation or a court order. 4.1.2 Consent may be 'implied' or 'explicit'. Implied consent can be signaled by the behavior of the patient and only has validity if the patient genuinely knows and understands what is being proposed.

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	4.1.3 Explicit consent is given verbally or in writing and incorporates written informed consent as defined in this Policy. Explicit consent when given verbally is to be documented in the patient's medical record. 4.1.4 Consent is a process and not a single event and requires continuing discussion with the patient that reflects the evolving course of care and treatment. 4.1.5 Every effort should be made to provide information to the patient in a language and in terminology that he/she can easily understand. 4.1.6 A competent adult patient has the right to refuse to consent to treatment or an intervention even if the consequences of such refusal are life threatening. In such cases the HCP is obliged to make reasonable attempts to ensure the patient understands the consequences, and that for clinical reasons such refusal may limit future treatment options.
4.2	**Valid Consent** Consent is valid only when the following elements are present: 4.2.1 Competency/Capacity: Patients/service users are to have the competency/ capability to understand the nature and consequences of a treatment decision and with the intellectual ability to reach a reasoned choice about treatment, including the capacity to understand the consequence of refusing treatment. Competency/ capacity may not be present if the patient is underage, mentally ill or disabled, under the influence of drugs or medication, under great stress or pain at the time of the consent, semi-conscious, or in labor. **Note: an assessment for competence/capacity may be carried out and documented by a healthcare professional** 4.2.2 Voluntariness: Patients/service users must be free to consent or to refuse treatment, free of undue influence or coercion. 4.2.3 Disclosure of Information: Valid consent requires disclosure of information that will ensure an "informed" consent. The information disclosed must include: 4.2.3.1 The known or suspected diagnosis and options for treatment or management: The intervention may be for diagnostic purposes in which case the possible or suspected diagnosis may be discussed. 4.2.3.2 Nature and purpose of the proposed intervention (diagnostic test, treatment, operation): Consent is to be specific for the proposed intervention. 4.2.3.3 Probable risks and benefits of the proposed intervention: Risks should be described in percentage or ratio terms where possible, rather than by subjective terminology, such as small risk, slight risk, and rare. A risk does not have to be life threatening to require disclosure. 4.2.3.4 Reasonable alternatives to the proposed intervention should be disclosed even if they are not part of the consulted HCP's privileging profile, or outside the scope of the license of the HCO where the HCP is working.

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	4.2.3.5 Who is to perform the procedure: The HCP should inform the patient as to whom the treating physician/HCP is if different from the HCP obtaining consent, or if there is likelihood that the procedure may involve a number of qualified HCPs. 4.2.3.6 Any change or extension from the specific treatment for which consent is given must be disclosed in advance if there is a possibility that it will happen. 4.2.4 Opportunity to ask questions: 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. A doctor cannot discharge the duty to inform simply by providing pamphlets about a proposed procedure. 4.2.5 Accuracy: The information disclosed must be accurate and free of misrepresentation of material information.
4.3	**Consent Giver** 4.3.1 An adult, 18 years of age or older, can give consent unless there is evidence that critical elements of valid consent are absent. 4.3.2 Any intervention regulating or assisting reproduction requires informed consent of a married couple, i.e. both the patient and their spouse. The husband's consent is not required when an intervention that may alter the reproductive status of the wife is required to treat a life threatening condition. The husband's consent is not required when prescribing medications to the wife that may, by their nature, delay or impede pregnancy when such medications are required for the treatment of a medical condition.
4.4	**Substitute Consent Giver for Incompetent Adults** 4.4.1 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. 4.4.2 The preference for selecting a consent giver should follow the order of: 4.4.2.1 A decision-maker duly appointed by the patient at such a time he/she was not incompetent. Ideally this appointment will be in writing and witnessed. 4.4.2.2 A guardian appointed by a court that has jurisdiction in Dubai or elsewhere in the United Arab Emirates. 4.4.2.3 An adult relative up to the fourth degree who has had substantial personal involvement with the patient in the preceding 12 months. The sequence of priority is: The husband if the patient is a married female, 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.

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	4.4.2.4 A Licensed Healthcare Professional who is responsible for the overall care of the patient and not responsible for the particular procedure.
4.5	**Substitute Consent Giver for Minors** 4.5.1 Consent for those less than 18 years of age is to be given, in sequence of priority, by the father, Legal Guardian, or Substitute Consent Giver. 4.5.2 Priority if the father is not present is in the following sequence: mother, brother, sister, uncle from fathers' side, uncle from mother's side, grandfather, grandmother, other relatives from father's side, other relatives from mother's side. 4.5.3 If the minor's parents are divorced, the parent who has custody is the appropriate person to give consent. The other parent has right to information regarding the child's medical condition and/or treatment. 4.5.4 A Legal Guardian may give consent. Legal Guardianship is recognized if authorized by a Court of Law in the jurisdiction of the minor's country of origin. 4.5.5 The Substitute Consent Giver must have assumed guardianship of the minor.
4.6	**Consent for Temporary Absence from Hospital for Minors and Incompetent Adults** 4.6.1 Consent must be obtained for a minor or an incompetent adult who is an inpatient of the HCO to be transported to, or participate in, activities outside the institution. 4.6.2 Consent must be obtained for a minor or an incompetent adult who is an inpatient of the HCO to 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 parent/substitute consent giver must supply the names, addresses, relationships and telephone numbers of such persons.
4.7	**Consent for Discharge of a Minor Unescorted by a Guardian** 4.7.1 Consent must be obtained from the guardian for the discharge of a minor child unescorted by a guardian. 4.7.2 Documented consent must be obtained prior to discharge, or in cases where this is not possible, telephone consent must be obtained as per clause 4.9. The guardian must provide the name and relationship of the person responsible for escorting the minor home.
4.8	**Intervention without Consent** 4.8.1 Treatment may be administered without consent in an emergency Life Threatening situation when the patient is not capable of providing consent and a substitute consent giver is not available for minors, the patient's condition poses a threat to life or health and such treatment cannot be delayed; the responsible 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 4.8.2 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

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	4.8.3 An intervention may be initiated without consent when the patient's illness is contagious and is a threat to public health and safety. 4.8.4 When an intervention is initiated without consent, the clinical circumstances and other relevant circumstances must be documented in the patient's medical record.
4.9	**Telephone Consent** 4.9.1 Telephone consent is to be avoided but if judged by the HCO to be a possible occurrence then the process for telephone consent must be defined in policy. 4.9.2 A substitute consent giver can give telephone consent provided the elements for a valid consent are present and the consent is witnessed. 4.9.3 Telephone consent is to be documented in the patient's medical record preferably on a purpose designed form. Documentation is to include as minimum: 4..9.3.1 Name of person providing information; 4.9.3.2 Name of consent giver and relationship to the patient; 4.9.3.3. Date and time; 4.9.3.4 Summary of information given; and 4.9.3.5 Name of witness. 4.9.4 The participation and identity of the witness must be explained to the consent giver. The witness verifies the identity of the consent giver, the identity of the patient, the planned intervention, the acknowledgment by the consent giver that adequate information about the procedure and alternatives has been given, and that the consent giver gives the consent voluntarily.
4.10	**Consent for Diagnostic Screening Tests** 4.10.1 Consent is required prior to performing serological testing for HIV, hepatitis B, hepatitis C and HTLV when performed for screening purposes. 4.10.2 The risks, possible harms and benefits of testing should be disclosed including the consequences if found positive. The physician must explain to the patient that as per UAE laws all positive cases must be reported to the relevant Health Authorities. Disclosure of information should include the consequences that can result against persons infected with certain diseases, including legal proceedings, suspension from work, and deportation of non-UAE citizens.
4.11	**Consent for photographs and promotional activities** Consent is required for photographs, videos and promotional activity. The purpose, time frame and process to be followed if a patient gives consent for photographs, videos and promotional activities must be defined.
4.12	**Witnessing Consent** 4.12.1 A witness to the consent may be required in some circumstances including but not limited to:

	4.12.1.1 Telephone consent; 4.12.1.2 Patient is visually blind; 4.12.1.3 Patient is illiterate and can't read and write; 4.12.1.4 Patient is physically compromised ; and/or 4.12.1.5 Patient is competent and can understand and acknowledge understanding, but physically is unable to talk or write. 4.12.2 The witness for the consent must be someone other than the primary operator for the intervention. 4.12.3 The signing witness must witness the discussion of the procedure as well as signing or marking of the forms. 4.12.4 When a translator is required, the translator should function as a witness.
4.13	**Consent Form Format** 4.13.1 A written informed consent should be documented on an Informed Consent Form that will become part of the Medical Record. There should also be a note in the Medical Record that an Informed Consent was taken. 4.13.2 All consent forms must be legible and include the following information: 4.13.2.1 The name and address of the HCO; 4.13.2.2 The patient's name, and medical record number; 4.13.2.3 Name of specific procedure, operation or treatment to be performed in full terminology; 4.13.2.4 No abbreviations should be documented on the consent form; 4.13.2.5 The anatomical side and site of surgery and when more than one procedure is to be performed, the procedures and/or the surgical locations must be clearly defined; 4.13.2.6 Name of HCP performing the procedure/operation; 4.13.2.7 Statement that procedure/operation, risks, benefits, and alternative methods were explained to the patient; 4.13.2.8 Listing of the main risks; 4.13.2.9 Details of associated costs for the operation, procedure or treatment; 4.13.2.10 Listing educational brochures or printed information, if provided; 4.13.2.11 Statement, if applicable, that other physicians may perform some of the surgical tasks; 4.13.2.12 Statement, if applicable, that non-physician practitioners may assist in some of the surgical tasks or administration of anesthesia; 4.13.2.13 Statement that the consent giver understands and agrees to the procedure; 4.13.2.14 Date, time, name and signature of the consent giver, and relation to the patient if applicable;

	4.13.2.15 Date, time, name and signature of the HCP verifying that the information was given and appears to have been understood by the patient; 4.13.2.16 Date, time, name and signature of witness if applicable, or translator if utilized 4.13.3 When the consent process is initiated or completed in a different facility from that where the stated intervention is to be performed then the HCO must have a documented process that defines how the consent is to be transferred from the referring facility to the facility where the intervention is to be performed. The consent process is to be documented in the patient's medical record of the referring facility; this may be a copy of the written informed consent form of the facility where the intervention is to be performed. If consent has been initiated but not yet given this should also be stated in the patient's medical record.
4.14	**Duration and Validity of Consent** 4.14.1 In general, and except as defined in section 4.13, consent remains valid and in effect until the patient revokes their consent, or there is a material change in circumstances including a change of the patient's condition such that the associated risk or benefit of the intervention is also changed. When significant material change occurs the patient is to be informed and a new consent is to be given. 4.14.2 Consent for specific treatment in an ambulatory setting is valid for the duration of the planned course of the same treatment except as defined in 4.14.1. 4.14.3 Consent for a specific surgical procedure is valid for up to 30 days from the time the consent was given except as defined in 4.14.1. 4.14.4 Consent is required for each emergency room visit where a procedure takes place; except as specified in 4.8. 4.14.5 Consent for treatment with blood components is valid any time during the patient's hospital stay. 4.14.6 Consent for dialysis is valid throughout the course of same treatment except as defined in 4.13.1.
4.15	**Electronic Informed Consent** 4.15.1 Electronic version of Informed Consent forms is an acceptable method for obtaining the patient's consent. 4.15.2 If the health facility is using electronic medical records, electronic signature is acceptable. 4.15.3 The following requirements must be available for Electronic Informed Consent to be accepted: 4.15.3.1 Signatures are obtained via an electronic device (tablet or signature pad) which is linked to the patient's electronic medical record (EMR); 4.15.3.2 A scanned copy of the patient's or Substitute Consent Giver's Emirates ID/passport must be saved in the EMR; and

	4.15.3.3 The signature obtained electronically must be verified with the signature available on the Emirates ID/passport for authentication purpose. 4.15.4 The content of the electronic Informed Consent forms must meet the same requirements as that of the manual consent mentioned in this document. 4.15.5 For storing and retrieving the Informed Consent form, the electronic medical system shall maintain records of each entry with identified authentication.
4.16	**Telemedicine Services** 4.16.1 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 such cases this should be noted in the patient's record. 4.16.2 The patient or Substitute Consent Giver must be made aware where recording devices are used and that the release of such recording data shall require written patient authorization. 4.16.3 The participation and identity of the patient and/or substitute consent giver must be confirmed prior to consultation and documented in the patient records. 4.16.4 The physician and/or health care professional must verify: 4.16.4.1 The identity of the person giving consent; 4.16.4.2 The patient on whom the intervention is to be performed; 4.16.4.3 The planned intervention and/or treatment ; 4.16.4.4 The consent giver and/or substitute consent giver acknowledges that adequate information about the procedure and alternatives have been given; and 4.16.4.5 The consent giver and/or Substitute Consent Giver gives the consent voluntarily 4.16.5 The participation and identity of physician and/or health care professional must be explained to the patient or Substitute Consent Giver. 4.16.6 The patient must be made aware and approval must be granted by patient or the Substitute Consent Giver of any other person present prior to their tele- consultation, intervention or treatment. 4.16.7 The patient or Substitute Consent Giver must be made aware and approval must be granted prior to the intervention or treatment, if a third remote site is participating in the tele-consultation. 4.16.8 Patient data may not be viewed by other remote networked location without the patient's or Substitute Consent Giver's consent. 4.16.9 Patient photographs, audio recording, or video recording must not be used without the patient's or Substitute Consent Giver's consent. 4.16.10 Documentation and completion of consent for the Tele-medicine intervention must 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 must also be documented and the information provided in order to obtain Consent (with limitations, if any)

5. DEFINITIONS & ABBREVIATIONS	
5.1	**Attending Physician/HCP**: physician or HCP who is responsible for the overall care of the patient.
5.2	**Consent:** A declaration of willingness to undergo a procedure, treatment, intervention or investigation which is evidenced in the patient record.
5.3	**DHCA**: The Dubai Healthcare City Authority established under Article (4) of the Law, and comprises the Chairperson, the DHCC Board of Directors and the Executive Body.
5.4	**DHCC**: Dubai Healthcare City
5.5	**DHCR**: is the regulatory arm of Dubai Healthcare City Authority. An independent licensing and regulatory authority for all healthcare providers, medical, educational and other business operating within DHCC.
5.6	**EMR:** Electronic Medical Record
5.7	**Explicit Consent:** when a person actively agrees, either verbally or in writing to undergo a specific medical intervention. See also
5.8	**General Consent:** Written consent, given by patient on initial contact with the Healthcare Operator to provide initial, non-specific care and services.
5.9	**Healthcare Operator (HCO):** any entity (hospital, clinic, laboratory, pharmacy or other) providing healthcare.
5.10	**Healthcare Professional (HCP):** in DHCC, a licensed HCP is a Healthcare Professional holding a License duly issued by the DHCA Licensing Board in accordance with the Professionals Regulations and the applicable Practice Rules
5.11	**HIV:** Human Immunodeficiency Virus
5.12	**HTLV:** Human T-Cell Lymphotropic Virus
5.13	**Implied Consent:** (1) the granting of permission for healthcare without a formal agreement between the patient and health care provider; (2) consent established when a patient's conduct indicates a willingness to submit to general medical treatment, for example, allowing vital signs to be monitored.
5.14	**Incompetent Adult:** 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.
5.15	**Informed Consent:** a process of communication between a person and a physician or other healthcare professional that results in the person's authorization or agreement to undergo a specific medical intervention. It includes the principle that a physician has a duty to inform his or her patients about the nature of a proposed or alternative treatment, procedure, test, or research, including the risks and

	benefits of each alternative and of not receiving it. An informed patient can then make a choice which procedure, if any, to undergo.
5.16	**Most Responsible Physician:** Physician who is responsible for the overall care of a patient.
5.17	**Substitute Consent Giver:** A person who is authorized 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) 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. b) A court appointed guardian in UAE or elsewhere. c) A parent for a minor (less than 18 years of age) d) The father even if he is less than 18 years of age e) In the absence of the father the mother can give consent even if she is less than 18 years of age f) If the Substitute Consent Giver is deemed incompetent an alternate Consent Giver should be sought
5.18	**Treating Physician/HCP:** physician or healthcare professional who is delegated responsibility for all or part of the care of a patient.

6. References

6.1	Schedule 2 (concerning Patients' Right and Responsibilities) of the Governing Regulation, Regulation number (1) of 2013, Dubai Healthcare City Authority
6.2	Federal Law No. (10) Of 2018, Concerning Medical Liability and the Cabinet Decision number (33) of 2009, promulgating the bylaw of the medical liability law
6.3	HAAD Guidelines for Patient Consent (January 2016)
6.4	DHA Guidelines of Patient Consent, 2019.
6.5	Federal Law No. (1) Of 2006, Concerning Electronic Commerce and Transaction.
6.6	Waikato District Health Board (2010). Informed Consent. Waikato District Health Board. Available on : https://www.waikatodhb.health.nz/assets/Docs/LearningandResearch/Research/3cc53b7c28/Informed-consent.pdf
6.7	Consumers Health Forum of Australia (2013). Informed Consent in Healthcare: An Issues Paper. Available on : https://www.chf.org.au/sites/default/files/informed_consent_issues_paper.pdf