



وزارة الصحة  
Ministry of Health

الدليل السعودي للإذن الطبي

# Saudi Guidelines for Informed Consent

First Edition  
1440H (2019G)



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## **A Letter from the Ministry of Health:**

As it is the concern of the Ministry of Health (MOH) in the Kingdom of Saudi Arabia to improve the patient experience through the provided health services and to increase the satisfaction level, they ensured to take on improvement projects and initiatives based on the global best practices in the healthcare field. Since we believe in the importance of empowering and involving patients with the treatment plan and dealing with it in line with the vision and in a way that ensures quality improvement and increases performance, we developed the Saudi informed Consent Guide which will significantly contribute to preserving the patient and family rights, and the practitioner as well as health care providers.

The need of developing this guide comes from the demand of involving patients or their representatives in many procedures and decisions related to their health condition, which will help to find radical solutions. Accordingly, this will have a massive impact on the increase in the satisfaction level of the health services and quality improvement at different health sectors around the kingdom.

## Introduction:

The Saudi Guidelines for Informed Consent emanates from an initiative adopted by the Patient Experience Center at the Ministry of Health, in cooperation with the Saudi Patient Safety Center approved by the Minister of Health Dr. Tawfiq Al-Rabiah, and participation of a group of physicians, health practitioners and administrators who have the experience in health care, patient rights and Sharia issues related to the informed consent.

This guide aims to preserve the patient, family rights on the one hand, and the healthcare practitioner and provider on the other hand. The need to develop this guide is that many procedures require engaging the patient, his guardian, or his representative in the health decision-making regarding their health status. It is also considered a parallel step of the progress and diversity of the health services provided with KSA. Furthermore, it is an evidence of the country's eagerness to protect human rights in event of wellbeing or sickness, while implementing the tolerant Islamic law regarding litigation between the patient and the healthcare provider in case of a medico-legal complaint or a claim of medical error.

The patient's condition, eligibility, and ability to give consent at the time is taken into consideration, or if there is a medical excuse, which may require patient's representative or not. In all conditions, the patient's interest always comes first. Efforts and alternatives, if any, are made available to the patient to alleviate their suffering, and the opportunity for him to choose with conviction and transparency, which helps -God willing - providing smooth healthcare and raise the satisfaction level of the patient and their family while allowing them to participate in the treatment planning as recommended in the latest global healthcare approaches.

This guideline also provides a comprehensive and simple reference that can be learned easily to tackle complex medical practice issues.

## **Acknowledgment:**

The Patient Experience Center thanks the First Health Cluster in Riyadh, represented by King Saud Medical City, for participating in reviewing the translation and proofreading of the guide.

The Patient Experience Center extends its sincere thanks to the Saudi Center for Patient Safety, especially the Director-General of the Saudi Center for Patient Safety, Dr. Abdullah Hawsawi, and all those who participated in this work and helped in preparing and releasing the Saudi Guidelines for Informed Consent, and we also thank all members of the Committee.

## Working Team:

The team consists of an elite group of physicians, health practitioners, and administrators with experience in health care field, patient rights, and sharia matters related to the informed consent. The team has long and varied experiences in the research methodology. Saudi Guidelines for Informed Consent included the study of the status quo and access to international experiences in the informed consent. Accordingly, they developed and modified the guidelines and it will be applied to health services provided by the Ministry of Health and the private health sector in KSA. It can also be applied to all health care facilities in KSA.

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## Vision:

*Saudi Guidelines for Informed Consent is issued to raise awareness by engaging patients, and their families in the health care according to our tolerant Sharia and international standards to be used as guidelines in all health institutions in KSA regions.*

## Mission:

*We are committed to developing the Saudi medical consent guide for the patient through the participation of persons with expertise in many fields and the community as a whole.*

## Goals:

*1-Developing the Saudi Guidelines for Informed Consent.*

*2-Sharing the medical opinion with the patient, his guardian, or his representative.*

*3-Raising awareness of the health practitioners and spreading the concept of the informed consent among community members.*

*4-Unifying the current informed consent forms.*

*5-Participating and benefiting from experts, scholars (Islamic Jurisprudence) and health practitioners.*

*6-Protecting the rights of the patient, the health care provider, and the health facility.*

## Definitions:

**1-General Informed Consent (for Registration/Admission):** Approval or refusal of the patient, his/her guardian, or his/her representative to receive the treatment service voluntarily by the health facility and his ability to communicate with health practitioners concerning the informed consent for any non-emergency medical procedure.

**2-Special Informed Consent:**

Approval or refusal of the patient, his/her guardian or his/her representative to receive the treatment service voluntarily by a licensed health practitioner and his/her ability to communicate with health practitioners concerning the informed consent to perform a specific medical intervention, provided that sufficient information on this non-emergency medical intervention, such as (surgery - anesthesia - blood transfusion, etc.), is provided to the patient.

**3-Informed Consent Documentation:**

Legal documented process regulates the conduct of medical relationship between the patient and the health practitioner or the treatment facility according to the laws, regulations and medical requirements. Informed consent documentation aims to explain the elements of the treatment agreement conducted between the patients and practitioner or treatment facility. Further, it guarantees the compliance of the parties with the non-emergency treatment agreement and resolves the conflict between the parties to the agreement by explaining the rights, duties, and obligations of each party towards the medical procedure taken and determined in advance. Moreover, it explains the method, mechanism, outcome, and possible complications of the procedure. The document issued by the medical institution is called "Informed Consent Document" where the title of medical consent must be pointed out.

**4-The Guardian:**

A person represents and gives Informed Consent on behalf of someone who lacks the capacity (mentally incompetent) or on behalf of a minor under 18-years old.

**5-Patient's Agent/ Representative:**

A person assigned by the patient with full mental capacity to act on his behalf regarding his medical procedures.

**6- Child:**

A person under the age of 18 years.

**7- Capable Individual:**

Mature adult, mentally competent adult (male or female).

**8- The Capability of an Underage:**

An underage with incomplete perception. However, the age of maturity is 18 years.

**9- Person lacking legal capacity:**

A person who lost his sense and ability to understand the speech or act in his/her own affairs. However, if someone lost his/her sense and perception at some point he will be treated as incompetent at that point, but if they regained sense and perception, they will be considered a capable individual.

**10-The Responsible Physician :**

A consultant or a specialist who is responsible for providing medical care, procedures, or operation at that time. However, he could be the treating physician.

**11-The Treating Physician:**

A physician who admits a patient under his name. He could be the responsible physician about a medical procedure for the patient.

**12-Intervention/Invasive procedure:**

Any medical procedure performed by a practitioner where a complication is considered possible to occur including, but not limited to, amputating, stings, or the insertion of any material into the patient's body.

**13-High-Risk Procedure:**

Any medical procedure holds potential by more than 50% of losing an organ or its function or death as one of the possible complications. In such cases, the patient must be clearly and explicitly informed.

**14-The Health Facility:**

Any licensed medical institution provides health services whether it is a clinic, general and private hospital, or others.

**15- Health Practitioner:**

Anyone with a license and eligible to practice and provide health services including the following: physicians,

dentists, pharmacists, health technicians in radiology, nursing, anesthesia, laboratory, pharmacy, optics, epidemiology, prosthetic limbs, physical therapy, dental treatment, CT-scans, nuclear treatment, laser machines, operations, psychologists, nutritionist, public health, midwifery ambulance services, speech and auditory therapy, vocational rehabilitation, vocational therapy, treatment in medical physics and others.

**16-Side Effects of Medicines:**

Unwanted effects of medicines that occur because of giving medication correctly in therapeutic medical based doses and by the medical rules and it may occur in varying degrees.

**17-Minor Complications:**

Unwanted harm to the patient resulted from the medical procedure or treatment that does not lead to the loss of an organ, its function or cause death. However, it is possible to occur permanent or temporary.

**18-Major Complications:**

Unwanted harm to the patient resulted from the medical procedure or treatment that may lead to loss of an organ, its function or cause death. However, it is possible to occur permanent or temporary.

**19-Medical Procedure:**

All actions taken by the practitioner including examination, assessment, diagnosis, or any medical intervention whether it is pharmaceutical, surgical, psychotherapy, or any similar procedure.

**20-Medical Case Manager:**

A responsible employee of following-up and coordinating all health services provided to the patient as well as facilitating that between all health service providers in the entire facility.

**21-Morbidity and Mortality Committee:**

A committee studies the causes of morbidity and mortality in-detail to analyze the possible reasons, take necessary preventive measures and improve the medical performance of the healthcare facility.

**22- Interpreter:**

A mediator who facilitates communication between the patient, his guardian, or his representative and the practitioner in case they speak different languages, this might include using sign language or any similar method, and the interpreter must be acceptable for both sides.

**23- Medical Team:**

A group of physicians and health practitioners responsible for all aspects of patient care by providing the necessary medical

interventions for the patient and following-up the case for a specific period.

**24-Technical or Regulatory Supervisory Entities:**

Entities who are following the progress of medical intervention in the health facility and guarantee that the patient is provided with medical services according to the applicable and agreed-upon standards, laws and regulations.

**25-Informed Consent Procedures:**

A detailed explanation provided by the physician or the health practitioner on the medical procedure and its expected benefits without exaggeration, the possibility of causing harm without attenuation or overstatement, and its alternatives if there are any, and all information that concern the patient.

**Definition of Informed Consent:**

Approval by the patient, his guardian, or his representative to the health facility or to the health practitioners performing all necessary procedures to maintain and recover the patient's health.

**Components of Informed Consent:**

1. Consent (the patient, his guardian, or his representative).
2. Authorized for (the healthcare facility or the practitioner).
3. Authorized action (the procedures required to maintain and regain health).
4. The format (indicate approval and consent – in verbal or written form).

**Conditions of Informed Consent:**

1. To be given by the authorized person.
2. The person who gives the Informed Consent must fulfill the legal capacity.
3. The consent procedure must be legitimate.
4. The consent shall be in a language to be understood by the patient, and shall be stated verbally in a clear manner.
5. The consent is valid until the end of the specified medical procedure.
6. The approval must be voluntary to the consent not forced.
7. It must be given while the patient is fully aware and conscious.

**Conditions of Medical Practitioners:**

1. The medical practitioner shall be qualified, licensed to practice and provide the specified medical services.
2. To aim for the benefit of the patient and act in their best interest.
3. To follow the known healthcare standards of the medical profession.
4. The medical practitioner shall not violate or exceed the boundaries of the medical consent, except in life-saving situations.

# Types of Informed Consent:

## I) Types of informed consent according to the subject:

### 1. Unrestricted consent:

It is the patient consent for the healthcare practitioner to perform any medical procedure to preserve or recover their health.

### 2. Restricted consent:

It is the patient consent for the healthcare practitioner to perform a specific medical procedure to preserve or recover their health.

\*Both types are valid whether it is unrestricted or restricted if the authorized procedure is legitimate.

## II) Types of informed consent according to the way of expression:

1. **Explicit verbal consent:** (for instance, the patient says to the practitioner “I give you a consent to perform a certain surgical operation or a certain examination”).

2. **Inexplicit consent:** (for instance, the patient approves to perform a specific examination or medical intervention, but then the physician finds out that the cause of the illness is different compared to the cause that the patient has been approved, In this case, the physician can proceed and perform the adequate medical procedure based on the inexplicit consent that was given by the patient). However, the medical procedure must be restricted to achieve health purposes to cure the patient.

3. **Signal consent:** (for instance, when the patient nods their head as a sign of approval).

4. **Written consent:** (for instance, when the patient writes his approval for medical procedures without any verbal words).

\*Anything indicating the approval of the patient is enough to obtain the consent to proceed with the medical procedure. However, this should be documented in the patient medical record.

**\*Patient silence shall not be considered a consent to perform any medical procedure.**

**Written informed consent shall be obtained in case of dangerous procedures, with the risk of any side effects that may occur to the patient, as follows:**

1. Any surgical operation, intervention, or hospital admission.
2. Giving any type of anesthesia (general, regional anesthesia, or procedural sedation).
3. Performing interventional exams.
4. Giving chemotherapy or radiotherapy.
5. Taking a photograph of the patient for therapeutic or educational purposes.
6. Utilizing body parts and tissues that have been removed during operations.
7. Training during the internship year or before it with the required of written informed consent for all disciplines.
8. Hemodialysis procedures.
9. Blood transfusion.
10. In case of compulsory admission for psychiatric patients, Mental Health Care Law is followed.

\*In case of conducting scientific research, medical research regulations and guidelines in the Kingdom of Saudi Arabia shall be followed.

# Guardianship of the Minor and the persons Lacking Legal Capacity:

## First: Guardianship in informed consent:

A legitimate legal authority enables its holder to undertake the personal and financial matters of a minor, person lacking legal capacity, or incapacitated patient.

### Guardian responsibility:

The guardian is responsible for providing the informed consent and treatment which serves the benefit of the minor, person lacking legal capacity, or incapacitated patient.

### Who is the guardian?

The guardian of minor is the father because of the relationship and near relative that cannot be detached.

## Second: The Guardians order:

The order of guardians in the right of informed consent for the ward is based on the order of the legitimate guardianship and according to its provisions.

### The guardian:

1. Father.
2. Grandfather ( Father side).
3. Mother.
4. Then to the closet male relatives.
5. The governor shall not be a guardian and there is no need to refer the matter to him unless there is no one from the patient's male relatives available.
6. If the patient is a rational, sane adult, then the informed procedure is a right of the patient, so no one can compel him to authorize, nor authorize on his behalf; Unless the medical procedure is necessary to save his life, it takes place without his consent, but if the patient is a minor, it is not permissible to perform the medical procedure for him except after the consent of his guardian, and after his interest is achieved except in cases upon which the saving of his life depends, the guardian's consent is not required; because it is not considered in this case. In the case of conflict between relatives in approval and disagreeing, then whoever had his opinion in the interest of the patient according to the physician's report is considered.
7. Consent of a capable patient is required, however, in case of they lack capacity or incapacitated the guardian's consent is imperative according to the legitimate guardianship order and its provisions in which serve the ward's benefits. Yet, if the guardian action may harm the ward, then the action is not considered valid and the right of giving the consent is shifted to another guardian then to the judge.
8. Article (9/15L): The psychiatric patient has the right to appoint a legal guardian to defend his rights within and outside the psychiatric treatment facility. The Local Council for Mental Healthcare manages the affairs of the psychiatric patient who is unable to make the decision and has no guardian about the therapeutic decisions until the appointment of a legal guardian.
9. Article (9/16L): Compulsory Decision form (1) and Compulsory Decision extension form (2) are used to inform the patient or his guardian on compulsory admission or to inform him of the method to be followed if he wishes to cancel the compulsory admission decision of the treatment facility.
10. If the psychiatric patient at the time of admission is unable to understand these rights, they are explained to him when his condition is improved by the members of the treating team and documented in the medical file.

## Third: Patients whose consents are deemed invalid:

1. Minors.
2. Unconscious patients.
3. Mentally incapacitated patients.
  - Patients with mental illness such as schizophrenia.
  - Patients with mental disabilities or dementia diseases that affect their perception, including:
  - Mentally retarded patients (moderate to severe).
  - Patients with dementia.

## Guardianship Expiration:

### **The guardian expires in the following cases:**

1. When a minor reaches maturity.
2. When unconscious person regains his consciousness.
3. Return to sanity and perception regarding those who suffer from an illness that affects mental state and perception.

**\*In the case where the guardian is absent, cannot be reached, or cannot wait for his attendance, a committee is convened at the healthcare facility and authorized to give the consent on his behalf. This committee must have the following characteristics:**

### **First: the committee membership**

1. Two specialized physicians who are not less than specialists and familiar with the medical condition.
2. Member or a representative of the medical administration.
3. Social worker.

### **Second: Convening of the committee:**

1. The committee shall be held at the request of the treating physician or his representative.
2. The request shall be issued through informing the facility's medical administration, or whoever represents it.
3. The committee shall be held as soon as possible to ensure meeting its needed purpose.

**Third: The committee could be permanent or temporary as the case requires, taking into consideration the provisions mentioned in the first and second paragraphs.**

**\*According to the Mental Health Care Law, the psychiatric patient shall be referred to the Local Council for Mental Healthcare to be a guardian for the patient in case of absence of the guardian or his representative.**

## Delegation and Authorization of Informed Consent to others:

The patient can authorize someone else to give the consent on his behalf provided that the authorizer and the authorized shall have full capacity and competence to give the informed consent. On the other hand, the medical procedure must be legally authorized.

### **First: Witnesses:**

Two witnesses should be testified, preferably healthcare practitioners, especially if the medical procedure is dangerous.

### **Second: Essentially, Informed consent is required except in the following cases:**

1. Emergency cases that include that threatening to the person's life or some of his important organs when consent cannot be obtained from the patient or his guardian.
2. Cases in which the public interest requires the need to treat or prevent, like contagious infectious diseases that poses a threat to the health of community members.
3. If the patient is suspiciously having a mental illness with clear indications that the person has a severe mental disorder where the symptoms of which potentially can harm them or harm the others at the time of their examination. they shall be treated or compulsory admitting them into the facility in an obligatory manner after taking the required procedures according to the mental health care law and its implementing regulations.

### **Third: Expiration of the informed consent:**

1. When the purpose is met or the specific period is expired: completion of the authorized procedure or complete discharge from the hospital.
2. If the patient is fully cured of the treated disease.
3. Death.

### **Fourth: Child maturity:**

Puberty is achieved by reaching 18 years old.

## Informed consent parties: roles and responsibilities:

**Director of the healthcare facility:** responsible for ensuring the safe therapeutic care is provided to the patients and ensuring the fulfillment of the essential safety requirement of the patient safety through an administrative and technical system and qualified licensed staff. Moreover, he is also responsible for implementing all informed consent procedures that are adapted in this guide within the facility.

**Quality or risk manager in the healthcare facility:** responsible for providing and updating policies and procedures of the informed consent in the healthcare facility and ensuring the compliance of practitioners with the policies of the Informed Consent Guide and related standards. The manager also must spread awareness about the policies between members of the medical and administrative team. However, he is responsible for monitoring the implementation of the informed consent procedures by the medical staff, and in case of any violation, he must report the incidence to the higher management to take an action.

**Managing directors and technical supervisors in the healthcare facility (medical director – director of nursing):** They all have the same level of responsibility in regards of making their subordinates aware of the informed consent policies, ensuring their attendance of training and that they have an equal sense of responsibility regarding the supervision and observation of the fulfillment of these policies in cooperation with other clinical department supervisors in the facility. The director of any administration or the supervisor must guarantee that all staff members are aware of the informed consent policies and include such policy in the orientation program for new physicians in the healthcare facility.

**Clinical department supervisors in the healthcare facilities (nursing supervisor, Chief medical officer, medical assistant):** the supervisor of the department is fully responsible for the professional clinical practice standards, guaranteeing the fulfillment of ideal standards and implementing policies and procedures. They are also responsible for the health staff activities within the department including informed consent procedures and ensuring the person approval is obtained before providing any medical examination or treatment.

**The health practitioner and health service providers:** all health practitioners and health service providers are professionally responsible for the quality service that is provided including taking the right consent procedures before any examination or treatment. All health practitioners and health service providers shall be aware of the informed consent and informed consent guide, policy, procedures, implementation and to report any incident or recent case regarding informed consent violation (e.g. incomplete the requirements of the informed consent, expiring its purpose, or the patient is not aware of the procedures).

**Technical and regulatory supervisory authorities outside the healthcare facility** (senior central management): responsible for reviewing the policies in the healthcare facility and ensuring that there is an Informed Consent Guide of Ministry of Health and it is being implemented in each department within the healthcare facility. Besides, monitoring the related effectiveness of policies and ensuring their implementation within the healthcare facility, receiving any informed consent incident, sentinel events, and conducting the necessary investigations to avoid and resolve it.

**The physician/dentist:** professionally responsible to explain the procedure to the patient, and to ensure that he has adequate information about the benefits, risks, and alternatives of the procedure, to help and guide him, his family or his representative in the approval or rejection process. Besides, he is responsible for documenting this procedure, all matters that have been discussed, and the results whether approved or not.

The physician in charge, holds the legal responsibility to prove if a patient questions or impeaches the verbal consent. For this matter, the consent is preferred to be written and signed by the patient or his representative in some therapeutic interventions that have serious risks and when it is necessary.

**Patient experience, social service, and patient affairs departments:** it is better to involve a representative of one of the mentioned departments or other members of the healthcare team to participate in the discussion with the patient or his guardian while taking the informed consent as they may be called witnesses when needed. The physician or any participant from the team must document this in the patient file. In addition, they are responsible to provide means to educate the patient and his family about the informed consent.

**Nursing:** they are responsible for ensuring that the treatment team applying the informed consent for the patients and they fulfill its requirements in the patient file before performing any procedure, documenting them in the nursing notes and informing the head of the department if it has happened otherwise.

**Witness:** a person who witnesses and signs the consent of the patient, his representative, or guardian to carry out the medical procedure. (He confirms the identity of the patient or his representative who signed the informed consent and his mental state and awareness of what he signed for at that time).

### Special Cases of Informed Consent:

Some patients may need to obtain informed consent in a different way due to losing one or more of the

conditions of the right informed consent that may require involving a third party to complete the procedure legally or to complete the medical procedure without the medical consent, such as the following cases:

### **One: informed consent regarding children under 18 years old**

Written or oral approval must be taken from the guardian or representative of the children who are under 15 years old, while who are 15-18 years old, a written or oral approval must be taken from the patient and his guardian or his representative, except in the following case:

- The therapeutic intervention is necessary and can't be postponed in order to achieve the physical and mental health interest of the patient in admission or compulsory treatment.

### **Two: saving lives and critical conditions:**

In cases of a disease, life-threatening injuries or an injury that may result in loss of an organ or its function, it is permissible for the physician to ignore taking an informed consent under the following conditions:

- 1) Inability to take consent from a patient because of his lack of capacity.
- 2) The absence of a patient guardian or his representative with the possibility of his condition getting worse because of delayed intervention.
- 3) If it is likely that without the medical intervention, a loss of an organ or its function or even death may occur.
- 4) A consensus of at least two specialist physicians and confirming the necessity of an immediate medical intervention after examining the patient.

In such cases, medical or surgical intervention can be performed without the need for informed consent. However, it must be documented in the patient file and informing the patient or his relatives upon their arrival about all procedures that had to be taken after the treatment<sup>1</sup>.

### **Three: informed consent of a pregnant patient**

- The informed consent is given by the pregnant patient herself if she has full capacity. It is not allowable to ignore her, and she has the right to choose the person who will give the consent on her behalf. For instance, her father, brother, husband, or anyone of her relatives whether it is a male or a female as long as the authorization was approved<sup>2</sup>.
- In cases of medical abortion and the mother health is at risk or there was a risk of losing her life, it is enough to take consent from her personally or from her representative.
- If the reason for abortion is life threatening fetal abnormalities, the consent of both the mother and the father is required. If the father approved the abortion while the mother rejected it, the mother opinion shall be prevailed. The abortion procedure must be completed before the 120th day of pregnancy.

### **Four: taking informed consent by force:**

- It is not allowed to force a patient or his relatives to give informed consent if the patient has refused with full capacity. This is deemed as a violation of the properly informed consent regulations.

### **Five: informed consent of a psychiatric patient**

Similar to any normal patient, informed consent, whether written or verbal, must be obtained from a psychotic patient regarding all medical interventions if the following conditions are met:

1. Meeting the requirements of full capacity, age and mental state like any other patient who is not psychotic.
2. The ability to fully understand all the given information about the disease and the treatment options.
3. The ability to choose between offered options, approving or refusing the treatment, or any other life matter independently.
4. The ability to estimate the consequences and complications of the medical intervention whether it is approved or not.
5. The condition does not need compulsory treatment or admission, and what is stated in the articles of mental healthcare and its regulations of ambulatory admission, compulsory reservation, its periods ... etc. (article 11, 12, 13, and 14). In addition, in relation to compulsory treatment based on article 17 of the psychological and health care law (article 17 L1 and article 17 L 2).

<sup>1</sup> Example (2): An injured person has been brought from the building and construction sites; the physician found the patient unconscious with no identity. Upon examination, he found a brain hemorrhage that requires immediate surgical intervention. After consultation with another physician, both physicians decided on the necessity of an urgent operation. All the procedures including the operation have been documented in the patient file. In the next day, the patient regained consciousness and his condition was explained to him and recorded in the file.

<sup>2</sup> Example (4): A 9-month pregnant lady came with embryonic fluid leakage; all vital signs of the embryo were stable permitting normal delivery. After examination, the gynecologist suggests to the husband doing a cesarean section giving that it is easier than normal delivery. The wife refused but the medical team tried again by telling the husband of possible harm to the baby and leading him to force his wife to do the unnecessary cesarean section even without taking the approval of the mother.

6. The medical team should not force the patient or his relatives to give consent.
7. In cases where the patient lacks the full mental capacity, a psychiatric physician must be consulted to give a medical report about the patient condition before taking informed consent is required<sup>3</sup>.

#### **Six: informed consent of treatment that results in infertility or sterility**

It is enough to obtain consent from a patient with full capacity in case:

- Not married status.
- In case of temporary fertility because of the treatment for both married men and women alike.

If the treatment may lead to permanent sterility and completely prevent reproduction while there is a necessity for the medical intervention, the informed consent is taken from a married male or female patient and they are asked to inform their spouse without the need for their approval.

#### **Seven: informed consent of an incapacitated adult and has no guardian or representative<sup>4</sup>**

- In such cases, it is necessary to contact with the medical administration and inform the administrative governor of the principality where the medical institution healthcare facility is located, or submit to the Local Supervisory Board in case of the psychiatric patient, to assign a representative for the patient, if any, or to enable the medical team to provide the necessary care, if it is not an emergency case.
- Basic and essential medical care is provided after an examination by two specialists and confirming the necessity of the treatment, documenting it in the patient file. However, the informed consent is not required in such cases.

#### **Eight: informed consent in cases of patients with unstable capacity due to temporary psychological state or drug effects**

##### **Temporary psychological disorders of a patient:**

- The decision-making ability of a patient may vary during different stages of the patient illness, caused by fear or pain. This could be a temporary state, therefore, taking the required measures must be taking to ensure that the patient is ready to give the informed consent at a proper time and to ensure that the patient mental state is stable while giving his informed consent.

##### **The effect of anesthetic drugs and medicines that may affect the mental abilities of a patient:**

- It is important to make sure that the patient is free from any drug effects that may affect the activity of the nervous system that may impact the patient's decision-making ability. For instance, narcotics, strong painkillers, such as opium, or other sedatives.

#### **Nine: Deaf and dumb patients and patients with communication difficulty informed consent:**

The medical team must provide maximum effort to communicate with deaf and dumb patients through the help of sign language specialist or using any available ways. If this was impossible, consent can be given by a guardian or a representative assigned by the patient himself.

If there is no guardian or inability to get in touch with him, the health facility administration is required to contact the administrative Governor to assign the patient representative and entitle the medical team to provide the minimum required treatment without the need of following the informed consent procedures.

#### **Ten: consent to carry out medical research on patients in the medical facility**

1. The researcher must follow the requirements of the implementing regulation of Research Ethics on Living Creatures (statement of the National Bioethics Committee).
2. The medical facility must ensure that all medical research procedures are legally complete and to ensure patient privacy and keep their information private during the research.
3. The medical facility is obligated to treat any possible complications that may occur because of patient participation in the research.

#### **Eleven: special consent of organ donation**

##### **Organ donation from a living person:**

- The healthcare facility must follow the standards of organ donation consent as mentioned in the organ donation procedure guide issued by the Saudi Centre for Organ Transplantation.

<sup>3</sup> Example (5): An adult patient suffering from schizophrenia and has a diabetic foot that needs surgical intervention to amputate the leg. The patient refused to give consent to do the surgery. Upon consultation with the psychiatrist, it was discovered that the patient was suffering from advanced stage schizophrenia and incapable of estimating the consequences or defining the suitable options for himself. This case was recorded in the patient file and informed consent was given by his brother to perform the operation.

<sup>4</sup> Example (7): An elderly patient with dementia who does not have any children was admitted to a hospital due to a stroke. That stroke resulted in difficulty swallowing which requires a feeding tube insertion. The medical team was unable to reach the patient's relatives, however, after getting the consent of the principality, the required medical care was provided to the patient including the surgical intervention without the need of following the informed consent procedures.

- The healthcare facility must confirm the capacity of the donor before starting any donation process and taking informed consent.
- The healthcare facility is obligated to treat any complication that is a consequence of the organ donation process if ever happened.

**Organ donation from a brain-dead person:**

- The healthcare facility and the concerned medical staff must confirm brain death according to the standards of the Saudi Center for Organ Transplantation.
- The healthcare facility must follow the standards of informed consent regarding organ donation as mentioned in the organ donation procedure guide issued by (the Saudi Center for Organ Transplantation).
- The healthcare facility must provide the usual medical care to brain-dead patients until the end of the donation process. Meanwhile, taking the patient dignity and psychological state of his relatives into consideration.

**Twelve: Special consent of cosmetic surgeries and procedures:**

**A) Remedial operations or procedures:**

Written approval must be taken from the adult patient or his guardian or his representative.

**B) Non-remedial operations or procedures (for cosmetic purposes):**

It depends on the extent of its need or necessity, and each case is taken separately, in which case what is stated in the first point about informed consent must be applied.

**C) Informed consent is not considered effective in cases where it has been forbidden, such as sex changes.**

## Informed Consent Documentation:

It is the process in which the health practitioner or the healthcare facility save the informed consent content and its procedures through writing, recording, or photographing to return to them whenever needed.

### First: Documentation legitimacy:

The verse of loan is the longest one in the Holy Quran and considered to be the basis of documentation system in Islam, in which Allah may be praised and exalted ordered people to document transactions be by writing them, as in the words of the Almighty “O you who have believed, when you contract a debt for a specified term, write it down. And let a scribe write [it] between you in justice;” {Quran 2:282}.

### Second: Types of Documentation:

**Informed consent documentation has two types:**

#### One: Legal documentation (legitimate/ lawful)

This is the most important type of documentation. It combines both rules of testimony and codification. However, this system is governed by the medical institutions and their legislative spheres and supervision.

#### Two: Customary/ verbal documentation

The verbal work of the medical staff or their institution to document a routine medical procedure that shall be done once the patient enters the facility of the medical institution. This may include laboratory tests, vaccinations, or any other documentation work that does not require registration of the person who holds the documentation validity by the policies and procedures.

**Customary documents:** It is the approved form that is issued by the ones who has the authority for medical documentation. It is attached to the official medical file, the paper allowed to be written by the patient personally and signed by him provided that these papers are explanatory and complementary to the official informed consent form and included within the patient progress follow-up notes.

The Fingerprint electronic signature of the informed consent that is included in the electronic file is subject to the Islamic law provisions and the applicable law in the Kingdom of Saudi Arabia. As for the informed consent for patients without limbs or those similar to them, it is by visual recording or audiobook saved electronically in the medical file with legal documentation for that.

### Three: Importance of documentation:

- The real foundation upon which the medical and legal authorities depend on to seek the legal authorization of the medical consent.
- It is a reliable legal document that is being taken with precision and validity in medical and legal institutions.
- Facilitates the implementation process of medical procedure, brings attention to the importance of strengthening the patient relationship with the medical staff and their institution, and emphasizes the importance of the patient's understanding of the medical procedure exact details.

### Four: Governance of the Medical Consent:

A set of laws, regulations, and decisions which aim to achieve quality and excellence of medical documentation by selecting the appropriate and effective methods to fulfill the plans and objectives of the documentation process. However, it monitors the finding systems that control the relationship between the primary parties of the documentation process which affects the performance. Furthermore, it includes the elements that reinforce the legal aspect of the medical institution and its relationships with the patient in the long term. It identifies the internal and external responsibilities and the responsible side while maintaining transparency, justice, patients and institutional rights, and the rights to question medical institutes when needed. Therefore, protecting the patient and the medical staff is achieved taking into consideration avoidance of exaggeration.

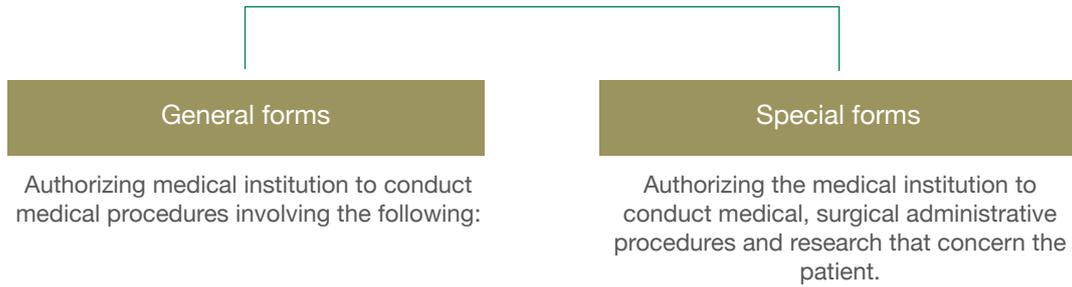
**The governance of the informed consent documentation must involve all the technical and legal details of the medical procedure consent document including:**

- 1) Detailed information about the medical institution, departments, and administration.
- 2) Day, date, and hour.
- 3) Detailed information about the patient.
- 4) Detailed information about the medical staff.
- 5) Detailed information about the medical procedure, the complications, risks, outcomes and alternatives.
- 6) Detailed information about the witnesses, the guardian, the representative, and the interpreter.
- 7) Make sure that the patient has received a copy of the consent to perform the medical procedure.
- 8) An original official form subjected to document control procedures within the institute.
- 9) The validity of informed consent must be specified.
- 10) The abbreviations may not be used in the document.

## Validity of forms signature

- 1) It must be issued by a medical institution registered with the Ministry of Health and government health sectors (according to the applicable law in the Kingdom of Saudi Arabia).
- 2) The medical and the administrative practitioners must be registered in the medical institution.
- 3) All the medical team must hold a valid license in the Saudi Commission for Health Specialties.
- 4) The patient who signs the consent must be in full capacity.
- 5) The legal guardian or the person representing the patient must hold the status of guardianship legally and attend what proves that. Or the presence of a representative of the patient for the mentally ill and those with special social cases, with the need for special forms to prove the representation of the patient.
- 6) The form must be within the period of its legal validity.
- 7) There must be a full harmony and concordance between the Arabic document and the interpreted one.
- 8) Forms should be observed to be suitable for people with disabilities.
- 9) Forms should be observed to be suitable for Injured people on the battlefield with an inability to identify their identity, expatriates with no guardian, and anonymous with unknown residence.
- 10) The medical team who is involved in the medical procedure is strictly prohibited to issue or to sign a form of participation in a medical procedure to their first-degree relatives.
- 11) Regarding the military field or civil (Relief) common operations, it is a must to follow unified forms for all teams which participate in the military medical and medical relief operations, however, it has to be approved by the concerned and related supervisory and leading authority of the military and civil medical procedures.
  - Regarding deaf, dumb and blind patients, the condition and the ability of the patient to communicate using sight, sound, writing, sign language, or Braille language is documented by specialists in communication with this category of patients or who represents them.
  - Documenting the informed consent through the electronic fingerprint and include it within the electronic medical record program for all medical centers and institutions in the kingdom.

## Informed Consent Forms<sup>5</sup>



- Giving therapeutic and diagnostic elements to the patient by mouth, anus, or by dermal, intramuscular, and intravenous injection.
- Blood sampling for laboratory examination.
- Radiation or scanning examination.
- Conducting an electrocardiography.
- Administration of fluids and drugs through intravenous cannulas.
- Applying splints.
- Dressing and disinfecting the wounds.
- Suturing the wounds and treating minor incisions.
- Discharging of cysts and minor abscesses.
- Removal of skin lumps and minor injuries.
- Taking specimens of superficial tissues.
- Insertion of nasal or gastrointestinal tubes for nutrition.
- Insertion of urinary Catheterization.
- Insertion of the arterial cannula for monitoring and taking blood gas samples.
- Dental procedures without sedation or general anesthesia.

### First: (Consent of general and medical routine procedures: Minimum content of the form):

Content	Explanation
Medical institution code	According to the officially applicable rules
Informed consent title	In both Arabic and English languages, with a bold and clear font.
Detailed information about the entity, department, and the physician.	Date/ department/ ward/ specialist or the physician name/ Job code/ contact number
General authorization formula.	In both Arabic and English languages. However, the explanation must include a consent acknowledgment to do all general and necessary medical procedures that are required to be admitted to the medical institution, the form may include acceptance of allowing trainees and students to participate in providing medical care.

Patient information	Full name ID number Medical file number Age/date of birth Signature/fingerprint Full name of the legal guardian, if necessary His relationship with the patient Guardian signature Date/time
Information about the documentation employee	Employee full name Employee No. Signature date/time
Additional instructions	Form validity General instructions about the patient's legal state and capacity.
Witnesses	The first and second witnesses: full name, signature, date, and time
Patient signature of receiving a copy of the Informed consent Form. "in case it requested"	

**Second: Consent that is supported by knowledge about the medical procedures or surgery:**

Content	Explanation
Medical institution code	According to the officially applicable rules
Informed consent title	In both Arabic and English languages, with a bold and clear font.
Detailed information about the authority, department, and the physician.	Date/ department/ ward/ specialist or the physician name/ Job code/ contact number
General authorization formula	In both English and Arabic languages, However, the explanation has to include an acknowledgment of the authority holder (the patient or his guardian and his relationship to the patient) general clarification of the procedure or the surgery and their details in both Arabic and English languages.
Physician clarification	Includes detailed information in both Arabic and English languages about the medical and surgical procedure, the results, and any possible complications. In addition, explaining in details to the patient about the alternatives, the risks, and complications of these alternatives, possible risks of not performing the procedure, and the chance to succeed. Also, providing the patient enough time to read and ask questions.
A special part in the consent for operations and high- risk procedures	Adequate explanation about the procedure or the operation, the reason why it was classified as high-risk, and the possible complications in a detailed and accurate manner.
Signature of the physician who took the consent	Employee full name Employee No signature date, time

Patient statement	Detailed information using legal phrases regarding the patient's understanding of the procedure or the surgical operation and its possible complications, including the fact that they were given enough time to explain and ask questions. Also, permit the medical institution to dispose of tissue and removed organs according to the Islamic law or the possibility of keeping them for educational purposes, if necessary.
Patient or legal guardian signature	Patient full name Signature Guardian or representative name and his relationship to the patient Signature Date, time
Interpreter statement, if necessary	Full name Employee No signature date, time
Emergencies	Part of the form is for the signature of the physician or the specialist to make an interventional procedure or surgery urgently to save the patient's life or to save one of his organs. It must include the acknowledgment of two specialist physicians in which one of them is at least is specialized: full name, Employee No, signature, date, and time.
Witnesses	The first and second witnesses: full name, signature, date, and time
Patient signature of receiving a copy of the Informed Consent Form	
The validity period of the form	Must not exceed 30 days as of the date of signature or what is required by the treatment plan.

**Third: Consent that is supported by knowledge about the procedures of electroconvulsive therapy- an electric shock for the psychiatric patient:**

Content	Explanation
Medical institution code	According to the officially applicable rules
Informed consent title	In both Arabic and English languages, with a bold and clear font.
Detailed information about the authority, department, and the physician.	Date/ department/ ward/ specialist or the physician name/ Job code/ contact number
General authorization formula	In both English and Arabic languages. However, the explanation has to include acknowledgment of the authority holder (the patient or his guardian and his relationship to the patient), general clarification about the treatment procedure using electric shock, number of sessions, treatment duration, and the possible results in both Arabic and English languages.
Physician clarification	Includes details in both Arabic and English languages and illustrative details of the medical procedure, the possible results and complications, details about the procedures of the sessions and benefits, alternatives, and related risks of using electric shocks, including the fact that everything was explained to the patient or his legal guardian (with clarification of the patient's capacity medically and legally). Also, the fact that he was given enough time to read and ask questions.

Signature of the physician who took the consent	Employee full name Employee No Signature date/time
Patient statement	Detailed information using legal phrases regarding the patient's understanding and the eligibility of the patient, his legal guardian, or his representative for signing the medical procedure, and its possible complications. Also, the fact that he was given enough time to read and ask questions.
Patient or legal guardian signature	Patient full name Signature Guardian full name and his relationship to the patient Signature Date, time
Interpreter statement and pledge, if necessary	Full name Employee No signature date, time
Witnesses	The first and second witnesses: full name, signature, date, and time.
Degree of confidentiality	High
Patient signature of receiving a copy of the Informed consent Form.	
The validity period of the form	Must not exceed 30 days from the date of signature or specified by the number of sessions.

**Fourth: Consent that is supported by knowledge about the chemotherapy procedures:**

Content	Explanation
Medical institution code	According to the officially applicable rules
Informed consent title	In both Arabic and English languages, with a bold and clear font.
Detailed information about the authority, department, and the physician.	Date/ department/ ward/ specialist or the physician name/ Job code/ contact number
General authorization formula	In both Arabic and English languages. However, the explanation must include the acknowledgment of the authority holder (the patient or his guardian and his relationship to the patient), general clarification of the chemotherapy procedure, its possible results, and whether it is a radical, secondary, or palliative treatment. All of that must be written in detail in both English and Arabic languages.
Physician clarification	Includes detailed information in Arabic and English languages, illustrative details about the procedure including the condition of the patient, the nature of the chemotherapy procedure, its possible benefits, the alternatives and related risks, the results, and the possible complications and details about the transparency of the physician explanation to the patient. Also, the fact that he was given enough time to explain and ask questions

Signature of the physician who took the consent	Employee full name Employee No signature date, time
Patient statement	Detailed information using legal phrases regarding the patient understanding of the mentioned medical procedure, its possible complications, the required precautions before and after the procedure. Also, the fact that he was given enough time to explain and ask questions.
Patient or legal guardian signature	Patient full name Signature Guardian full name and his relationship to the patient Signature Date, time
Interpreter statement and pledge, if necessary	Full name Employee No signature date, time
The witnesses	The first and second witnesses: full name, signature, date, and time.
The validity period of the form	Must not exceed 30 days from the date of signature or specified by the number of sessions.
Patient signature of receiving a copy of the Informed consent Form. "in case it requested"	

**Fifth: Consent that is supported by knowledge about the radiotherapy procedures:**

Content	Explanation
Medical institution code	According to the officially applicable rules
Informed consent title	In both Arabic and English languages, with a bold and clear font.
Detailed information about the authority, department, and the physician.	Date/ department/ ward/ specialist or the physician name/ Job code/ contact number
General authorization formula	In both Arabic and English languages. However, the explanations must include the acknowledgment of the authority holder (the patient or his guardian and his relationship to the patient), general clarification of the radiotherapy procedure, its possible results, and whether it is a radical, secondary, or palliative treatment. All of that must be written in detail in both English and Arabic languages.
Physician clarification	Includes detailed information in Arabic and English languages, illustrative details about the procedure including the condition of the patient, radiotherapy procedure, its possible benefits, the alternatives, and related risks, the results, the possible complications and the required precautions before and after the procedure and details about the transparency of the physician explanation to the patient. Also, the fact that he was given enough time to read and ask questions.

Signature of the physician who took the consent	Employee full name Employee No signature date, time
Patient statement	Detailed information using legal phrases regarding the patient understanding of the medical procedure, its possible complications. Also, the fact that he was given enough time to explain and ask questions.
Patient or legal guardian signature	Patient full name Signature Guardian full name and his relationship to the patient Signature Date, time
Interpreter statement, if necessary	Full name Employee No signature date, time
Witnesses	The first and second witnesses: full name, signature, date, and time.
The validity period of the form	Must not exceed 30 days from the date of signature.
Patient signature of receiving a copy of the informed consent form. "in case it requested"	

**Sixth: Consent that is supported by knowledge about Hemodialysis procedures:**

Content	Explanation
Medical institution code	According to the officially applicable rules
Informed consent title	In both Arabic and English languages, with a bold and clear font.
Detailed information about the authority, department, and the physician.	Date/ department/ ward/ specialist or the physician name/ Job code/ contact number
General authorization formula	In both Arabic and English languages. However, the explanation must include the acknowledgment of the authority holder (the patient or his guardian and his relationship to the patient), general clarification of the hemodialysis procedure and the fact that it is not a radical treatment of kidney failure but merely eliminating and discharging waste products and fluids outside the body. All of that must be written in detail in both English and Arabic languages.
Physician clarification	Includes detailed information in Arabic and English languages, illustrative details about the procedure including the condition of the patient, hemodialysis treatment procedure, its possible risks and complications during or after hemodialysis, possible benefits, alternatives, and short or long-term risks and details about the transparency of the physician explanation to the patient. Also, the fact that he was given enough time to read and ask questions.
Signature of the physician who took the consent	Employee full name Employee No signature date, time

Patient statement	Detailed information using legal phrases regarding the patient understanding of the medical procedure, possible complications, and the fact that he was given enough time to explain and ask questions.
Patient or legal guardian signature	Patient full name Signature Guardian full name and his relationship to the patient Signature Date, time
Interpreter statement, if necessary	Full name Employee No signature date, time
Witnesses	The first and second witnesses: full name, signature, date, and time.
The validity period of the form	Must not exceed 30 days from the date of signature or the number of sessions.
Patient signature of receiving a copy of the Informed consent Form. "in case it requested"	

#### Seventh: Consent supported by knowledge about Peritoneal Dialysis procedures:

Content	Explanation
Medical institution code	According to the officially applicable rules
Informed consent title	In both Arabic and English languages, with a bold and clear font.
Detailed information about the authority, department, and the physician.	Date/ department/ ward/ specialist or the physician name/ Job code/ contact number
General authorization formula	In both Arabic and English languages. However, the explanations must include the acknowledgment of the authority holder (the patient or his guardian and his relationship to the patient), general clarification of the Peritoneal Dialysis and that it is not a radical treatment of kidney failure but to eliminate and discharge waste products and fluids from the body. All of that must be written in detail in both English and Arabic languages.
Physician clarification	Includes detailed information in Arabic and English languages, illustrative details about the Peritoneal Dialysis including its possible risks and complications during and after hemodialysis, possible benefits, the alternatives, and short and long-term risks. and details about the transparency of the physician explanation to the patient. Also, the fact that he was given enough time to read and ask questions.
Signature of the physician who took the consent	Employee full name Employee No signature date, time
Patient statement	Detailed information using legal phrases regarding the patient's understanding of the medical procedure, its possible complications. Also, the fact that he was given enough time to explain and ask questions.

Patient or legal guardian signature	Patient full name Signature Guardian full name and his relationship to the patient Signature Date, time
Interpreter statement, if necessary	Full name Employee No signature date, time
Witnesses	The first and second witnesses: full name, signature, date, and time.
The validity period of the form	Must not exceed 30 days from the date of signature or by the treatment procedure.
Patient signature of receiving a copy of the Informed consent Form. "in case it requested"	

**Eighth: Consent supported by knowledge about receiving diagnostic examination in nuclear medicine:**

Content	Explanation
Medical institution code	According to the officially applicable rules
Informed consent title	In both Arabic and English languages, with a bold and clear font.
Detailed information about the authority, department, and the physician.	Date/ department/ ward/ specialist or the physician name/ Job code/ contact number
General authorization formula	In both Arabic and English languages. However, explanations must include the acknowledgment of the authority holder (the patient or his guardian and his relationship to the patient), general clarification about the medical procedure of using radioactive materials for examination whether introduced through the mouth or the vein, and any other examination related to this procedure. All of that must be written in detail in both English and Arabic languages.
Physician clarification	Includes detailed information in Arabic and English languages, illustrative details about examination using radioactive material including its possible risks and complications during or after examination, possible benefits, the alternatives, and short and long-term risks. And details on the transparency explanation to the patient. Also, the fact that he was given enough time to read and ask questions.
Signature of the physician who took the consent	Employee full name Employee No signature date, time
Patient statement	Detailed information using legal phrases regarding the patient's understanding of the medical procedure, its possible complications, and the fact that he was given enough time to explain and ask questions.

Patient or legal guardian signature	Patient full name Signature Guardian full name and his relationship to the patient Signature Date, time
Interpreter statement, if necessary	Full name Employee No signature date, time
Witnesses	The first and second witnesses: full name, signature, date, and time.
The validity period of the form	Must not exceed 30 days from the date of signature or the number of sessions.
Patient signature of receiving a copy of the Informed consent Form. "in case it requested"	

**Ninth: Consent supported by knowledge about receiving diagnostic Medical Imaging with contrast examination:**

Content	Explanation
Medical institution code	According to the officially applicable rules
Informed consent title	In both Arabic and English languages, with a bold and clear font.
Detailed information about the authority, department, and the physician.	Date/ department/ ward/ specialist or the physician name/ Job code/ contact number
General authorization formula	In both Arabic and English languages. However, explanations must include the acknowledgment of the authority holder (the patient or his guardian and his relationship to the patient), general clarification about the nature of the medical imaging, type and the contrast dye that is being used. All of that must be written in detail in both English and Arabic languages.
Physician clarification	Includes detailed information in Arabic and English languages, illustrative details about medical imaging procedures, type of the used dye, and its related risks. The procedure must include a chart of surveying questions to collect the related necessary information (with Yes/No) Checklist. The site where the dye will be injected in, type of the dye, the amount of the injected material, possible benefits, the alternatives, and related risks. and details about the transparency of the physician explanation to the patient. Also, the fact that he was given enough time to read and ask questions.

Signature of the physician who took the consent	Employee full name Employee No signature date, time
Patient statement	Detailed information using legal phrases regarding the patient's understanding of the medical procedure, its possible complications. Also, the fact that he was given enough time to explain and ask questions.
Patient or legal guardian signature	Patient full name Signature Guardian full name and his relationship to the patient Signature Date, time
Interpreter statement, if necessary	Full name Employee No signature date, time
The witnesses	The first and second witnesses: full name, signature, date, and time.
The validity period of the form	Must not exceed 30 days from the date of signature or by the procedures only.
Patient signature of receiving a copy of the Informed consent Form. "in case it requested"	

**Tenth: Consent supported by knowledge about magnetic resonance medical imaging procedures:**

Content	Explanation
Medical institution code	According to the officially applicable rules
Informed consent title	In both Arabic and English languages, with a bold and clear font.
Detailed information about the authority, department, and the physician.	Date/ department/ ward/ specialist or the physician name/ Job code/ contact number
General authorization formula	In both Arabic and English languages. However, explanations must include the acknowledgment of the authority holder (the patient or his guardian, and his relationship to the patient), general clarification of the magnetic resonance imaging procedure. All of that must be written in detail in both English and Arabic languages.

Physician clarification	Includes detailed information in Arabic and English languages, illustrative details about the magnetic resonance imaging procedure. The procedure must include a chart of surveying questions to collect all related necessary information (with Yes/No). Another chart to inspect the related safety and risk procedures. (checklist) and details about the transparency of the physician explanation to the patient. Also, the fact that he was given enough time to read and ask questions.
Signature of the physician who took the consent	Employee full name Employee No signature date, time
Patient statement	Detailed information using legal phrases regarding the patient's understanding of the medical procedure, its possible complications. Also, the fact that he was given enough time to explain and ask questions.
Patient or legal guardian signature	Patient full name Signature Guardian full name and his relationship to the patient Signature Date, time
Interpreter statement, if necessary	Full name Employee No signature date, time
Witnesses	The first and second witnesses: full name, signature, date, and time.
The validity period of the form	Must not exceed 30 days from the date of signature.
Patient signature of receiving a copy of the Informed consent Form. "in case it requested"	

#### Eleventh: Consent supported by knowledge about in-vitro fertilization and embryo transfer:

Content	Explanation
Medical institution code	According to the officially applicable rules
Informed consent title	In both Arabic and English languages, with a bold and clear font.
Detailed information about the authority, department, and the physician.	Date/ department/ ward/ specialist or the physician name/ Job code/ contact number

General authorization formula	In both Arabic and English languages. However, explanations must include the acknowledgment of the authority holder (the patient or his guardian and his relative relationship to the patient), general clarification of the couple knowing about the Fertilization procedure, and transferring the fertilized ovum into the Fallopian tube. All of that must be written in detail in both English and Arabic languages.
Physician clarification	Includes detailed information in Arabic and English languages, illustrative details about the procedure including the condition of the female patient, the nature of the procedure, its possible benefits, and the alternatives, the results, and possible complications. and details about the transparency of the physician explanation to the patient. Also, the fact that he was given enough time to read and ask questions.
Signature of the physician who took the consent	Employee full name Employee No signature date, time
Husband and wife statement	Detailed information using legal phrases regarding their understanding of the medical procedure and its possible complications, besides the fact that they were given enough time to explain and ask questions.
Signature of the couple	Husband full name Wife full name Signature The guardian is deemed invalid for both. Date/time
Interpreter statement, if necessary	Full name Employee No signature date, time
The witnesses (preferably one of the patient's relatives)	The first and second witnesses: full name, signature, date, and time.
The validity period of the form	Must not exceed 30 days from the date of signature.
Patient signature of receiving a copy of the informed consent form.	

**Twelfth: Consent supported by knowledge about organ or tissue donation procedures:**

Content	Explanation
Medical institution code	According to the officially applicable rules
Informed consent title	In both Arabic and English languages, with a bold and clear font.
Detailed information about the authority, department, and the physician.	Date/ department/ ward/ specialist or the physician name/ Job code/ contact number

General authorization formula	In both Arabic and English languages. However, the explanation must include the acknowledgment of the authority holder (the patient or his guardian and the relationship to him), general clarification about the organ or tissue donation procedure. All of that must be written in detail in both English and Arabic languages.
Physician clarification	Includes detailed information in Arabic and English languages, illustrative details about the organ or tissue donation procedure including the patient's condition, consequent results, the alternatives, the related risks, and possible complications, details about the transparency of the physician explanation to the patient and giving him enough time to read and ask questions. Explaining the possible psychological risks, the donor expected future health problems, available alternatives for the recipient, and the donor's right to change his mind about donation at any given time.
Signature of the physician who took the consent	Employee full name Employee No signature date, time
Patient statement	Detailed information using legal phrases regarding the patient understanding of the medical procedure, its possible complication, and the fact that he was given enough time to explain and ask questions.
Patient or legal guardian signature	Patient full name Signature Guardian full name and his relationship to the patient Signature Date, time
Interpreter statement, if necessary	Full name Employee No signature date, time
The donor relation to the patient	
The witnesses (preferably one of the patient's relatives)	The first and second witnesses: full name, signature, date, and time.
The validity period of the form	Must not exceed 30 days from the date of signature.
Patient signature of receiving a copy of the Informed consent Form.	

**Thirteenth: Consent supported by knowledge about organ or tissue transplantation procedures:**

Content	Explanation
Medical institution code	According to the officially applicable rules
Informed consent title	In both Arabic and English languages, with a bold and clear font.
Detailed information about the authority, department, and the physician.	Date/ department/ ward/ specialist or the physician name/ Job code/ contact number
General authorization formula	In both Arabic and English languages. However, explanations must include the acknowledgment of the authority holder (the patient or his guardian and the relationship to the patient), general clarification about the organ or tissue transplantation procedure All of that must be written in detail in both English and Arabic languages.
Physician clarification <sup>6</sup>	Includes detailed information in Arabic and English languages, illustrative details about the condition of the patient, the nature of the organ or tissue transplantation procedure, the consequent results, the alternatives, the related risks, and possible complications. And details about the transparency of the physician explanation to the patient and giving him enough time to read and ask questions. It also includes the explanation of the patient's medical history, the organ age, and condition, the risk of having some infectious disease or the ones that cannot be predicted by the donor, psychological and social risks resulted from the donation process, the predicated survival rate, and the expected and actual length of stay in the hospital. Also, mentioning the expected percentage of transplant rejection and the potential cost of immunosuppressive drugs (for uninsured patients).
Signature of the physician who took the consent	Employee full name Employee No signature date, time
Patient statement	Detailed information using legal phrases regarding the patient understanding of the medical procedure, it is possible complications and the fact that he was given enough time to explain and ask questions.
Patient or legal guardian signature	Patient full name Signature Guardian full name and his relationship to the patient Signature Date, time

Interpreter statement, if necessary	Full name Employee No signature date, time
The witnesses (preferably one of the patient's relatives)	The first and second witnesses: full name, signature, date, and time.
The validity period of the form	Must not exceed 30 days from the date of signature.
Patient signature of receiving a copy of the Informed consent Form.	

**Fourteenth: Consent supported by with knowledge about Blood / Blood components Transfusion procedures:**

Content	Explanation
Medical institution code	According to the officially applicable rules
Informed consent title	In both Arabic and English languages, with a bold and clear font.
Detailed information about the authority, department, and the physician.	Date/ department/ ward/ specialist or the physician name/ Job code/ contact number
General authorization formula	In both Arabic and English languages. However, an explanation must include the acknowledgment of the authority holder (the patient or his guardian and his relationship to the patient), general clarification about the procedure of transfusion of blood, or its Components. All of that must be written in detail in both English and Arabic languages.
Physician clarification	Includes detailed information in Arabic and English languages, illustrative details about the transfusion of blood or its components procedure, the condition of the patient and the need for blood transfusion or its components, the consequent results, the alternatives, the related risks, and possible complications and details about the transparency of the physician explanation to the patient, and giving him enough time to read and ask questions.
Signature of the physician who took the consent	Employee full name Employee No signature date, time
Patient statement	Detailed information using legal phrases regarding the patient understanding of the medical procedure and its possible complications and the fact that he was given enough time to explain and ask questions.
Patient or legal guardian signature	Patient full name Signature Guardian full name and his relationship to the patient Signature Date, time

Interpreter statement, if necessary	Full name Employee No signature date, time
The witnesses (preferably one of the patient's relatives)	The first and second witnesses: full name, signature, date, and time.
The validity period of the form	Must not exceed 30 days from the date of signature.
Patient signature of receiving a copy of the Informed consent Form.	

**Fifteenth: Consent supported by knowledge about anesthesia and sedation procedures:  
General/ local anesthesia/ Spinal anesthesia/ epidural anesthesia/ sedation**

Content	Explanation
Medical institution code	According to the officially applicable rules
Informed consent title	In both Arabic and English languages, with a bold and clear font.
Detailed information about the authority, department, and the physician.	Date/ department/ ward/ specialist or the physician name/ Job code/ contact number
General authorization formula	In both Arabic and English languages. However, the explanation must include the acknowledgment of the authority holder (the patient or his guardian and his relative relationship to the patient), general clarification about the anesthetic procedure, sedation and nature, and type of these procedures (general anesthesia, local anesthesia, spinal anesthesia, epidural anesthesia, and sedative drugs). All of that must be written in detail in both English and Arabic languages.
Physician clarification	Includes detailed information in Arabic and English languages, illustrative details about the condition of the patient and the nature of the anesthetic procedure, the consequent results, the alternatives, the related risks, and possible complications and details about the transparency of the physician explanation to the patient and giving him enough time to read and ask questions.
Signature of the physician who took the consent	Employee full name Employee No signature date, time
Patient statement	Detailed information using legal phrases regarding the patient understanding of the medical procedure, its possible complications. Also, the fact that he was given enough time to explain and ask questions.
Patient or legal guardian signature	Patient full name Signature Guardian full name and his relationship to the patient Signature Date, time

Interpreter statement, if necessary	Full name Employee No signature date, time
The witnesses (preferably one of the patient's relatives)	The first and second witnesses: full name, signature, date, and time.
The validity period of the form	Must not exceed 30 days from the date of signature.
Patient signature of receiving a copy of the Informed consent Form.	

**Sixteenth: Consent supported by knowledge about giving patient's information and data outside the domain of the direct medical care chain:**

**Provided that all the private/confidential information of the patient are not disclosed and that the disclosure is only for its intended purpose as follows:**

- 1) To report a death resulting from a criminal incident or to prevent the commission of a crime and may not be disclosed in this case only to the relevant official authorities.
- 2) To report a communicable or infectious disease.
- 3) If the practitioner is defending a charge by the patient or his family related to his competence or his professional practice.
- 4) To protect the patient or others from any risk.
- 5) If the patient/guardian agrees in writing to disclose it or disclosure to the patient's relatives is useful for treatment.
- 6) If he is ordered to do so by a judicial authority.

Content	Explanation
Medical institution code	According to the officially applicable rules
Informed consent title	In both Arabic and English languages, with a bold and clear font.
Detailed information about the authority, department, and the physician.	Date/ department/ ward/ specialist or the physician name/ Job code/ contact number
Required data	In both English and Arabic languages. However, an explanation must include adequate legal clarification of the required data and the reasons related to their demands in both Arabic and English languages.
Patient or legal guardian signature	Patient full name Signature Guardian full name and his relationship to the patient Signature Date, time
Interpreter statement, if necessary	Full name Employee No signature date, time
Signature of the patient affairs manager	Full name Employee No signature date, time official seal

Witnesses	The first and second witnesses: full name, signature, date, and time.
The validity period of the form	Must not exceed 30 days from the date of signature.
Patient signature of receiving a copy of the Informed consent Form. "in case it requested"	

**Seventeenth: Consent supported by knowledge about the rejection of examination and treatment:**

Content	Explanation
Medical institution code	According to the officially applicable rules
Informed consent title	In both Arabic and English languages, with a bold and clear font.
Detailed information about the authority, department, and the physician.	Date/ department/ ward/ specialist or the physician name/ Job code/ contact number
Required data	<p>Set the terms regarding common medical procedures that are being refused including:</p> <ul style="list-style-type: none"> <li>· Refusal of transfusion of blood or its components.</li> <li>· Refusal of clinical examination.</li> <li>· Refusal of the treatment, with clarification of the treatment type.</li> <li>· Refusal of surgical procedure with an explanation.</li> <li>· Refusal of taking a sample for examination with an explanation.</li> <li>· Refusal of radiological examinations with an explanation.</li> </ul> <p>Using proper legal phrases for disclaiming responsibility of the medical institution and the staff for any complication that may occur because of the refusal, written in both English and Arabic languages.</p>
Patient or legal guardian signature	<p>Patient full name Signature Guardian full name and his relationship to the patient Signature Date, time</p>
Interpreter statement, if necessary	<p>Full name Employee No signature date, time</p>
Exception	Special cases for lifesaving or organ-saving are excluded.
The witnesses. "if any"	The first and second witnesses: full name, signature, date, and time.
The validity period of the form	Must not exceed 30 days from the date of signature.
Patient signature of receiving a copy of the Informed consent Form. "in case it requested"	

**Eighteenth: Consent supported by knowledge about participation in a research study:**

Content	Explanation
Medical institution code	According to the officially applicable rules
Informed consent title	In both Arabic and English languages, with a bold and clear font.
Detailed information about the authority, department, and the physician.	Date/ department/ ward/ specialist or the physician name/ Job code/ contact number
The approval number that is issued by the research ethics committee for scientific research	
General authorization formula	In both Arabic and English languages. However, explanations must include the acknowledgment of the authority holder (the patient or his guardian and his relationship to the patient), general clarification about the procedures that are related to the research study written in both Arabic and English languages.
Researcher clarification	Includes detailed information in both Arabic and English languages related to the scientific research procedure and the policy of the medical institution in the scientific research (giving the patient Arabic and English copies) with an accurate description of the goals, procedures and consequent results of the scientific research, the related alternatives, and risks, possible complications, and services that will be offered to the patient in return. Further, and details on the transparency explanation to the patient and the fact of giving him enough time to read and ask questions. The patient has the right to end his participation and quit the study providing that the medical services offered to the patient won't get affected. In addition to explaining the patient role in the research and informing him to maintain the confidentiality and security of information.
Signature of the researcher who took the consent	Employee full name Employee No signature date, time
Patient statement	Detailed information using legal phrases regarding the patient understanding of the medical and research procedure, its possible complications, and that he was given enough time to explain and ask questions.
Patient or legal guardian signature	Patient full name Signature Guardian full name and his relationship to the patient Signature Date, time
Interpreter statement	Full name Employee No signature date, time
The witnesses "if necessary"	The first and second witnesses: full name, signature, date, and time.
The validity period of the form	Must not exceed 30 days from the date of signature.

Patient signature of receiving a copy of the Informed consent Form. "in case it requested"	
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**Nineteenth: Consent supported by disclaimer and knowing about photographic digital photography, cinematographic and video recording, as well as using, storing, and retrieving of this data:**

Content	Explanation
Medical institution code	According to the officially applicable rules
Informed consent title	In both Arabic and English languages, with a bold and clear font.
Detailed information about the authority, department, and the physician.	Date/ department/ ward/ specialist or the physician name/ Job code/ contact number
Required data	<p>Set terms regarding necessary data and informative procedures to be used including:</p> <ul style="list-style-type: none"> <li>· Photographic images</li> <li>· Digital images</li> <li>· Video recording</li> <li>· Digital recording</li> <li>· Cinematography</li> <li>· Data storing and restoring</li> <li>· Satellite broadcasting (live or recorded) or through the internet.</li> <li>· Broadcasting site, border, and details of the broadcast.</li> </ul> <p>Using legal phrases in Arabic and English for disclaiming responsibility of the medical institution and the staff in which the patient entitles the medical institution and its staff to use these data according to the terms within the agreement (newspapers- research magazines-medical books-satellite broadcast channels –internet).</p> <p>and details on the transparency explanation to the patient and giving him adequate time to read and ask questions.</p> <p>The patient has the right to end or quit participation in the agreement at any time without affecting the provided medical services.</p>
The purpose	
Patient or legal guardian signature	<p>Patient full name</p> <p>Signature</p> <p>Guardian full name and his relationship to the patient</p> <p>Signature</p> <p>Date, time</p>
Interpreter statement, if necessary	<p>Full name</p> <p>Employee No</p> <p>signature</p> <p>date, time</p>
Disclaim responsibility and pledge not to reveal the patient identity and not to use it for a purpose other than that agreed upon.	
Witnesses	The first and second witnesses: full name, signature, date, and time.

The validity period of the form	Must not exceed 30 days from the date of signature.
Patient signature of receiving a copy of the Informed Consent Form. "in case it requested"	

**Twentieth: Consent supported by knowledge about the medical-dental procedure:**

Content	Explanation
Medical institution code	According to the officially applicable rules
Informed consent title	In both Arabic and English languages, with a bold and clear font.
Detailed information about the authority, department, and the physician.	Date/ department/ ward/ specialist or the physician name/ Job code/ contact number
General authorization formula	In both Arabic and English languages. Explanations must include the acknowledgment of the authority holder (the patient or his guardian and his relationship to the patient), general clarification about the medical and surgical dental procedure, and its details in both English and Arabic languages.
Physician clarification	Includes detailed information in Arabic and English languages about illustrative details of the medical and surgical dental procedure, its results, possible complications, details about the patient's need for anesthesia or sedation, the treatment plan, and details on the transparency explanation offered to the patient and giving him enough time to read and ask questions.
Signature of the physician who took the consent	Employee full name Employee No signature date, time
Patient statement	Detailed information includes legal phrases regarding the patient understanding of the medical-dental procedure and its complications and the fact that he was given enough time to explain and ask questions.
Patient or legal guardian signature	Patient full name Signature Guardian full name and his relationship to the patient Signature Date, time
Interpreter statement	Full name Employee No signature date, time
The validity period of the form	Must not exceed 30 days from the date of signature.

# Simplified Form to Unified Informed Consent Process within the Healthcare Facilities:

## First: Purpose

Unify the process of informed consent in the healthcare facility.

## Second: Policies and Procedures

- 1) Healthcare facilities must provide a suitable environment when meeting the patient to take the informed consent.
- 2) Healthcare facilities must set policies and procedures to be followed whether the informed consent is signed or not.
- 3) Healthcare facilities must introduce the healthcare practitioners and entitle them to implement the policies and procedures of informed consent.
- 4) The physician or his deputy must explain the medical procedure before taking the informed consent from the patient, his guardian, or his representative.
- 5) Healthcare facilities must follow a process that ensures easy delivery of the medical procedure information to the patient, his guardian, or his representative before taking the informed consent.
- 6) The rights and obligations of the patient, his guardian, or his representative shall be taken into consideration when obtaining the informed consent.
- 7) Healthcare facilities must protect the rights of medical practitioners.

## Third: Procedures:

- 1) Informed consent place: At an office, emergency department clinic, a ward or the patient room, depending on what is suitable and accessible for the case.
- 2) Convenient atmosphere with various amenities.
- 3) The patient privacy shall be taken into consideration.
- 4) Reachable place for the patient and the medical team.
- 5) The Attendance is limited to the concerned medical team and whoever the patient desire to attend from his side.

## Requirements to be fulfilled:

- Education tools and devices shall be provided to facilitate an explanation of the medical procedure.
- Illustrative diagrams of the procedure in the informed consent paper if necessary.
- In case of implantation of tools or devices in the patient body, the tools, and devices themselves or a photo showing them must be displayed while taking the informed consent.
- Availability of a presentation tool to demonstrate the nature of the medical procedure.
- Providing suitable documents (software or hardware) to take the informed consent and all the required stationaries.

## Fourth: Medical Team:

- 1) The physician who performs the medical procedure or someone to represent him.
- 2) If more than one specialty is required, the physician or someone to represent him from the involved specialties shall be present.
- 3) The medical team members from other specialties who are involved in the medical procedure.
- 4) An interpreter if the physician and the patient have no ability to speak the same language or a sign language specialist if necessary.
- 5) Medical case manager or his representative to arrange the meeting.
- 6) Any team members should not attend if the patient does not want his attendance.
- 7) Make sure that only the eligible person is authorized to explain the informed consent.

**Medical team ethics:**

- Confidentiality and not to reveal the patient information.
- Not to violate the patient privacy.
- Deliver the information professionally and suitably, and not using incomprehensible medical terms.
- Make sure that the patient understands the medical procedure by explaining the treatment, the plan, and the options available in an understandable way.
- Inform the patient of the importance of his opinion and that he is a partner of the treatment plan.
- Avoid the attendance of unwanted companion by the patient during the meeting.
- Not to exaggerate or underestimate the expected complications and the benefits of the treatment.
- Advising the patient to take any decision instead of enforcing him.
- Making sure that the medical procedure matches the information that the patient signed upon on the informed consent.

Taking into consideration the lack of conflict in the opinions of the medical team before the patient or speaking in a foreign language. In addition to, avoid taking any action that was not signed with approval.

**The dialogue and discussion**

- Dialogue and communication skills of the medical team with the patient.
- Choosing the proper time to make the discussion with the patient and medical team.
- The physician must be in a comfortable state to ask the patient for informed consent.
- Considering the professional communications in clear and understandable way to the patient, his guardian, or his representative.
- The medical team shall introduce themselves to the patient, showing their ID cards and verify the patient identity.
- Making sure that the patient understands the medical procedure before signing.
- Asking the patient to explain the medical procedure.

**Patient negative behavior and how to handle it:**

- Crying (express compassion and concern for the patient and reduce his anxiety).
- The patient raising his voice (keep calm and show sympathy toward the patient in an appropriate way).
- Committing an assault toward the medical team (beforehand preventive measures such as availability of security if needed).

**Complications of the procedure, treatment alternatives, and expected response ratio that should be mentioned:**

- All major complications that are more than 1% likely to occur and minor ones more than 5% likely to occur.
- Complications that occur directly after the procedure and the ones that occur later (within 30 days after the procedure).
- The expected response percentage (success of the procedure).
- Different treatment alternatives accessible in the same facility or elsewhere according to the medical team knowledge.

**Fifth: Patient:****Conditions for whom entitled to take the treatment permission:**

- Male or female patient with full capacity and awareness.
- In case of a child patient, one of the parents, preferably the father.
- In case the patient in coma state with no relatives while two specialist physicians of the same specialty agreed the importance of an intervention and the patient shall be notified of it later.
- Children whose parents have divorced; the decision is taken by the child guardian (refer to the guardian part in the informed consent).

**Patient rights in taking the informed consent:**

- The patient has the right to choose the physician according to the available capabilities of the healthcare facility

and the adopted policy of distributing cases to doctors.

- The patient is entitled to the necessary treatment for his condition, respecting his right to refuse and interfere in his condition in the case of life-saving , emergency intervention, or compulsory treatment. Not neglecting him if he refuses any of the medical procedures.
- Knowing the other treatment alternatives available at the facility or elsewhere according to the offered information for the treatment team.
- The patient has the right to take the opinion of another physician according to the capabilities and the availability of the appropriate health services.
- All expected complications must be explained to the patient while mentioning its incidence rate including major ones that are 1% or more likely to occur and minor ones that are more than 5% likely to occur.
- Giving the patient a suitable time limit to think before deciding on the medical consent.
- Cancellation of the consent of medical procedure after the sign.

#### **Patient's obligations for the informed consent:**

- 1) The patient signature is necessary whether he accepted it or rejected it.
- 2) It is necessary to read the consent carefully, understand the medical procedures, and inquire before signing.
- 3) It is necessary that the patient, his guardian, or his representative disclose the health problems and medical history that affect the medical procedure.
- 4) Commitment to the medical procedure instructions.

#### **The result (approval and refusal):**

Procedures and actions after taking the patient's approval:

- Documenting the consent by writing it clearly in the patient file.
- Starting to prepare the patient for the medical procedure.
- Considering psychological and religious support of the patient.

#### **Procedures and actions after taking the patient refusal:**

- Respecting the decision of the patient, his guardian, or his representative. Also, giving medical advice when necessary.
- Re-explain the medical procedure and clarification of the complications that may occur if the procedure was not conducted.
- Make sure that the patient understands the consequences and risks and ask him to explain them.
- Patient signature of rejection with a declaration of the consequent complications if the procedure was not carried out.
- His rejection must not affect his right to receive other treatment services.
- Considering the religious and psychological support according to the reason for rejection.
- Re-explain the alternative medical procedures.

## **Sixth: Responsibilities**

### **Administration of the facility**

- Making sure all the practitioners know the medical procedure consent policies.
- Ensuring that the medical procedure consent policy is followed and implemented by all the staff in the hospital as part of the patient's rights.
- Measuring the quality of the informed consent.
- Evaluating patient experiences with the informed consent.
- Improving patient experiences and quality of the informed consent.
- Protecting of the practitioner right in case of unexpected complication happened, knowing that it was mentioned to the patient in the informed consent and the physician followed the known scientific procedure, in such case, the facility holds the responsibility to defend the practitioner in front of the judiciary.

### **Department heads:**

- 1) Making sure that all the staff in the department recognizes and implements the policy.
- 2) Providing prepared forms for common procedures in the department or taking forms presented by a specialized

scientific associations.

- 3) Measuring the quality of informed consent in the department.
- 4) Evaluating patient experience related to their department.
- 5) Improving patient experiences and quality of the informed consent in the department.
- 6) Activating the role of the audit committees in reviewing cases, morbidity, and mortality to distinguish between complications and medical errors periodically and in line with safety standards and CBAHI requirements. Also, to protect the rights of both patients and practitioners.

#### **Physicians and nursing**

- 1) Physicians, nursing, and medical staff cooperate to make sure of the written and signed patient consent before the procedure date according to the policy of the informed consent, written with time being specified.
- 2) The nursing makes sure that the written consent exists in the patient's medical file, complete and signed by the patient, his guardian, or his representative.
- 3) Medical Records and Information System Department.
- 4) Making sure that all consents of patients who went through an operation in the hospital are included in the patient's file.

#### **Forms:**

- Unifying the forms of the informed consent.

## Appendix (1):

### Recommendations that require attention when taking informed consent:

#### First: mistakes in choosing the medical team

- Unnecessary attendance of a medical team member.
- The absence of the physician who is responsible for the case or someone to represent him.
- Conflict of opinions between the medical team members during the meeting.
- The presence of unwanted practitioner by the patient.
- The physician failure to attend the meeting.
- Entitle another physician who lacks information about the procedure and not the physician himself to explain it.
- The absence of an interpreter despite the need.

#### Second: medical team mistakes during the discussion:

- Filling the informed consent form before meeting the patient.
- Frequent interruption of the patient.
- Failure to verify the patient's identity.
- Giving wrong information to the patient
- Failure to follow the ethical dialogue when discussing with the patient.

#### Third: Mistakes from the patient side

- Failure to sign the refusal to carry out the medical procedure.
- Signing without reading the informed consent form.
- Hesitation of making the medical procedure to approve or refuse (a time limit is given depending on the case) before having the committee opinion.
- Taking another information and patients experiences in non-medical procedures.

#### Fourth: medical team common mistakes

- Failure to document the informed consent in the patient file.
- Performing unnecessary medical procedures not included in the form signed by the patient.
- Failure to clarify the major and expected complications in case the patient refused to do the medical procedure or to sign.
- Failure to ensure the understanding of the patient, his guardian, or his representative to what was explained to them.
- Using medical terms or words that are not comprehensible to the patient.
- Asking to sign informed consent as a routine procedure.

#### Fifth: Common mistakes in choosing a place

- The existence of something that distracts or prevents the patient from understanding.
- The existence of something that violates the privacy of the patient during the process of explaining the medical procedure.
- The presence of people or relatives that the patient does not want them to know about his condition.
- Unreachable place.

#### Sixth: Common mistakes from patient side:

- Failure to sign the refusal or acceptance to carry out the medical procedure.
- Signing without reading the informed consent form.
- Hesitation of making the medical procedure to approve or refuse (a time limit is given depending on the case) before having the committee's opinion.
- Taking another information and patients experiences in non-medical procedures and based on these the patient accepts the informed consent or rejects it.

**Additional notes:**

- Training on the informed consent procedures is deemed a part of the professional training for every practitioner, however, the head of the department sets all the requirements and submits them to the training department that organizes training programs about the informed consent regularly, also there should be on site training to ensure that these procedures are being implemented.
- The practitioner has to make sure that the patient is capable of understanding all the given information, however, there might be a need for an interpreter if the patient speaks a different language to interpret all the written information and help the patient to give the right consent.
- The practitioner must act within his authority and not accept any sort of pressure by anyone to acquire a patient's consent to perform a procedure that he does not feel competent to do. However, he must communicate with the director for consultation and support.
- It is necessary for the practitioner to document the patient's consent by writing all the discussions that have led to the approval using the consent form and documenting them in the patient's notes even in cases of procedures requiring verbal consent.

The guide will be updated and we are pleased to receive your suggestions so that the committee can review the proposals and include them in updated version via the following e-mail

**[Consent-Guidelines@moh.gov.sa](mailto:Consent-Guidelines@moh.gov.sa)**

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