

MATERNITY AND CHILDREN HOSPITAL QUALITY MANAGEMENT AND PATIENT SAFETY Quality and Patient Safety Administration Policy Title: INFORMED CONSENT IPP Policy Number OPS-006 Page 1 of 12 Issuing No. Version 2 Applicable To: All Medical Workers Replaces No. Effective Date 02/30/2024 3 Revision Date 01/25/2027 Approval Date 01/30/2024 1.0 PURPOSE 1.1 To provide the patient with the information they need in order to make the right decision regarding his/her own health and medical condition(s).3.2 Tabuk Maternity and Children Hospital Official Informed Consents are as follows: 3.2.1 General Consents (GDOH-COR-GC-351) 3.2.2 Surgical and Medical Interventional Procedure (GDOH-COR-SMIP-353) 3.2.3 High-Risk Patient/Procedure/Treatment 3.2.4 Anesthesia/Sedation Consent (GDOH-COR-ASC-355) 3.2.5 Blood Transfusion Consent (MCH-T-CBCT-002) 3.2.5.1 Consent for Blood/Blood Components Transfusion 3.2.5.2 Consent for Blood/Blood Components Transfusion without NAT Testing 3.2.5.3 Patient Relative Unable to Consent for Blood/Blood Components Transfusion 3.2.6 Consent for Photographic and/or Electronic Recordings (GDOH-COR-CPER-365) 3.2.7 Radiology Consent 3.2.7.1 Consent for Radiology Contrast Procedure (Intravenous/Intra-Arterial) 3.2.7.2 Pregnancy Consent in Radiology Department 3.2.8 Informed Consent for Patient Examination by Trainee.5.0 ATTACHMENTS: 5.1 General Consents (GDOH-COR-GC-351) 5.2 Surgical and Medical Interventional Procedure (GDOH-COR-SMIP-353) 5.3 Anesthesia/Sedation Consent (GDOH-COR-ASC-355) 5.4 Consent for Photographic and/or Electronic Recording (GDOH-COR-CPER-365) 5.5 Consent for Blood/Blood Components (Mch-T-CBCT-002)3.13.5 Consent for Photographic and/or Electronic Recordings: 3.13.5.1 The patient can authorize the physician for the use of any media/photos of The procedure is for legal/medical purposes, provided that the patient's identity is not disclosed.Epidural Injections and Anesthesia 3.16.1.11 Fine Needle Aspiration 3.16.1.12 Hemodialysis and Peritoneal Dialysis (acute or chronic) 3.16.1.13 Invasive radiological procedures (e.g., angiography, angioplasty, drainage of an abscess under CT guidance) 3.16.1.14 Lumbar Puncture 3.16.1.15 MRI Examination 3.16.1.16 Node Removal 3.16.1.17 Oral Surgery (removal lesions) 3.16.1.18 Percutaneous aspiration of body fluids or air through the skin (e.g., arthrocentesis, bone marrow aspiration, lumbar puncture, chest tube, paracentesis) Removal of Foreign Body 3.16.1.19 Suprapubic Taps 3.16.1.20 Surgical removal of root tip or teeth, including plastic recap 3.16.1.21 3.16.1.22 Swan Ganz insertion 3.16.1.23 Treatment with Chemotherapy and Radiation Oncology Procedures 3.16.1.24 Use of Radioactive Material 4.0 Proceedings 4.1 Ask all patients admitted as inpatients to sign the General Consent 4.2 Request all patients receiving care for the first time in the outpatient clinics for admission to sign a general admission consent form.3.16.1 List of High-Risk Treatment and Procedures Requiring Informed Consent, including, but not limited to, the following: 3.16.1.1 All Surgical Procedures Performed Inside the Operating Room 3.16.1.2 All types of anesthesia, including Conscious Sedation 3.16.1.3 Arterial Infusion 3.16.1.4 Biopsy (e.g., bone marrow, breast, liver, kidney, prostate) 3.16.1.5 Blood and Blood Products Administration @Clustertabulk.1.6 3.16.1.6 Central Line Placement 3.16.1.7 Closed Reduction 3.16.1.8 CT Examination with Contrast 3.16.1.9 Endoscopy (e.g. colonoscopy, bronchoscopy, cystoscopy, J-Tube) 3.16.1.10 placement, nephrostomy).2.6 Consent for Blood/Blood Components Transfusion 2.6.1 I consent authorizing the physician to order blood and blood products transfusion as part of treatment during admission 2.7 Nucleic Acid Amplification Testing (NAT) 2.7.1 This

is a highly sensitive method of blood testing used to detect Hepatitis C virus (HCV), Human Immunodeficiency Virus (HIV-1), and West Nile Virus (WNV) in blood.

## 2.2 General Consent

### 2.1.2 Consent given by the patient or his/her legal guardian authorizing his/her attending physician to provide medical, nursing, and other clinical, diagnostic, or therapeutic procedures with the exception of surgical and invasive procedures, induction of anesthetics, infusion of blood and blood products, and other procedures that require special consent.

## 3.4 Women's Consent

### 3.4.1 An adult mentally sound woman has the right to consent to medical procedures intended to be done on her body, including surgical operations, except for procedures like aesthetic/cosmetic surgery and those relating to reproduction, such as use of contraceptives, hysterectomy, or any other procedures specifically leading to infertility. The admission and registration staff is responsible for ensuring that the General Consent for admission is signed by the patient or his/her legal guardian or next of kin.

## 4.6 The need for the form and complete consent must be fully explained to the patient, and a translator should be made available if the patient cannot speak Arabic or English and to clarify specific aspects.

## 4.7 The attending physician and admitting officer is responsible for ensuring that a substitute decision maker is designated by the patient in writing on the official consent form and that the relationship, ID, and contact numbers of the substitute decision maker are obtained and documented in advance.

## 3.8 All consents are legal documents that must be written in Arabic and English and must be completed in Arabic and English.

## 3.9 The physician should provide the patient with comprehensive information about the medical procedure he is about to perform, what is required of him, and the consequent risks and complications that might occur.

### 4.9.1.1.4 Lifesaving Operation: In a high-risk case with no guardian available, the consent must be signed by the treating consultant and two (2) other physicians before the operation starts.

## 4.10 Informed Consent for Patient Examination by Trainee:

### 4.10.1 The Most Responsible Physician (MRP) Treating Physician should:

#### 4.10.1.1 Manage the process for signing the informed consent by the patient.

## 2.3 Surgical and Medical Interventional Procedure

### 2.3.1 Consent for any surgical procedure (minor and major), including the use of any media or photos of the procedures either in OPD, ER, and in-patients for legal/medical purposes, provided the patient's identity is not disclosed.

## 3.5 Special Cases

### 3.5.1 When a patient is incapable of giving informed consent (e.g., minors or mentally incompetent patients), consent is sought from the next of kin or legal guardian. He should be capable of thoroughly comprehending and understanding the information provided to him, so that he may give his consent voluntarily, with complete content and awareness, and without any deception or pressure.

## 3.13.6 Radiology Consent

### 3.13.6.1 Consent for Radiology Contrast Procedure (Intravenous / Intra-Arterial)

#### 3.13.6.1.1 A radiologist is required to obtain a patient's informed consent before the procedure using contrast.

#### 3.13.6.2 Pregnancy Consent in the Radiology Department.

## 2.4 High-Risk Consent

### 2.4.1 This consent must be taken in cases of serious, complicated, risky, or new surgeries, for removing any organ, or for high-risk patients proceeding with surgery/procedure, despite any abnormal parameters of the patient.

## 3.0 Policy

### 3.1 Informed consent is always obtained before any invasive surgery/procedure, sedation/anesthesia, and transfusion of blood and blood components.

## 3.6 Emergency Cases

### 3.6.1 Consent in emergency situations: In cases where a patient is in peril, dying, or imminent serious harm, death is expected, the physician may perform the necessary medical procedure immediately without

waiting for consent if he has reason to believe that saving the life of a patient or preventing serious harm is an overwhelming probability.3.10 The physician must disclose in a reasonable manner all significant medical information that he believes is relevant and essential in making an informed decision for the patient in deciding whether or not to undergo the procedure. Informed consent is obtained from the family after explaining the possibility of risks, complications, drawbacks, potential benefits, possible alternatives, likelihood of success, possible problems related to recovery, and possible results of no treatment.3.13.5.2.1 A consent authorizing to carry out blood transfusion without a NAT test in case of life-threatening situations 3.13.5.3 Patient/Relative Unable to consent for Blood/Blood Components Transfusion. Tabuk Health Cluster 4.9.2.1.1.3 High-risk anesthetist and surgeon must explain the exact condition of the patient to the guardian before signing the consent for high-risk, unfit, or very risky anesthesia. 1.2 To provide guidelines and procedures for healthcare professionals on how to obtain informed consent from the patient based on the standards.2.5 Anesthesia / Sedation Consent 2.5.1 I consent authorizing the anesthetist to perform anesthesia sedation and any further emergency measure/s or anesthesia technique/s as may be found necessary during the medical procedure.3.3 Adults Consent 3.3.1 All statements in the consent forms must be thoroughly explained to the adult (18 years old and above) and mentally sound patient, whether male or female, or their legal guardian/representative (with valid ID).3.13.2 Surgical and Medical Interventional Procedure 3.13.2.1 This consent is valid for sixty (60) days or when the patient or relative changes their decision during a single admission stay in the hospital.3.13.3 Anesthesia Consent 3.13.3.1 Informed consent for anesthesia is obtained from the patient/family after explaining the anesthesia plan, risks, benefits, and alternatives 3.13.3.2 Anesthesia consent is valid for ninety (90) days.3.13.6.2.1 A radiologist is required to obtain a patient's informed consent before the procedure for pregnant patients to help prevent accidental irradiation of an unrecognized pregnancy.4.5 The admission and registration staff must inform the patient and/or his/her legal guardian or next of kin to sign the consent form.4.8 The healthcare provider performing the operation or special procedure must obtain consent for surgery or special procedures.4.9.1.1.7 Documents that the informed consent was obtained and ensures that the patient understood the information 4.9.1.1.8 Ensures that informed consent is complete and valid before the patient is taken to the operating theater for surgery or procedure.4.9.1.1.10 The patient authorizes the physician for the use of any media/photos of the procedures for legal/medical purposes, provided that the patient's identity is not disclosed.4.9.2 For Operational Consent 4.9.2.1 The treating physician has the duty to disclose all information relevant to the patient's decision and to obtain the patient's informed consent.2.0 DEFINITIONS: 2.1 Informed Consent 2.1.1 A person's voluntary agreement with sufficient mental capacity and full knowledge of the risks involved and probable consequences.3.7 For both special and emergency cases, consent will be signed by two (2) consultants (e.g., surgeon and anesthetist prior to emergency intervention).3.10.3 The benefits of the proposed procedure, as well as the frequently occurring significant risk of the proposed treatment and alternatives.3.12 The physician must obtain informed consent witnessed by the nurse or midwife involved in patient care.3.13 Consents: Special Considerations 3.13.1 General Consents 3.13.1.1 This consent is valid for a single admission only.3.13.2.1.1 Operation Consent 3.13.2.1.1.1 The surgeon performing a surgical procedure on a

patient is responsible for obtaining the patient's informed consent prior to surgery.3. 13.7 Informed Consent for Patient Examination by Trainee 3. 13.7. 1 An informed consent is signed upon admission prior to the patient examination.3. 16 The hospital has a policy and forms for obtaining informed consent from the patient or a legal representative prior to starting high-risk treatments and procedures.4.9 The nurse's role in informed consent: 4.9. 1 To verify with the patient if the physician has discussed the following: 4.9. 1. 1 Explained each treatment or procedure in a language the patient (or legal guardian) can understand; 4.9. 1. 1. 1 Diagnosis and the nature of the proposed treatment. 1.3 To provide information to healthcare professionals that seeking informed consent is a process.3. 10.5 The patient or the patient's legal guardian/representative should be given the opportunity to ask questions and receive additional information as requested 3. 11 The patient should be completely aware of the intended medical intervention.3. 13.2. 1. 1.2 Additional procedures must be listed in the consent form.3. 13.4 Blood Transfusion Consent 3. 13.5. 1 Consent for Blood/Blood Components Transfusion Elements of Patient Consent include: 3. 13.5. 1. 1 Description of the transfusion process.3. 13.5.2 Consent for Blood/Blood Components Transfusion without NAT.3. 13.5.4 This consent is valid for sixty (60) days or when the patient or relative changes decision during a single admission stay in the hospital.All procedures requiring consent will be informational, based on their health or medical records.4. 10. 1.2 Explain to the patient upon admission the possible participation of a postgraduate trainee in his/her treatment.If the procedure is canceled or rescheduled for whatever reason, a new consent must be obtained.3. 13.3.3 The consent process is documented and witnessed.3. 13.5. 1.2 Identification of the risks and benefits of the transfusion.3. 13.5. 1.3 Identification of alternatives, including the consequences of refusing the treatment.4.9. 1. 1.5 Prognosis of alternative treatment, including no treatment, so as to enable the patient to make an intelligent and informed decision to undergo such treatment.It is the responsibility of the staff nurse involved in the patient's care to witness the signature of the physician and the patient or responsible individual giving consent.4.9.2. 1. 1 The nurse checks the consent for: 4.9.2. 1. 1. 1 Elective Cases: Both major and minor cases must have consent signed by the patient or guardian 4.9.2. 1. 1. 2 Emergency Cases must have a consent signed by the patient or guardian.Most traditional screening tests require the presence of antibodies to trigger a positive test reaction.In case of life-threatening situations, two (2) physicians will sign consent.3. 15 The disclosure process is documented in the patient's medical record.4.9. 1. 1.2 The prognosis of the proposed treatment 4.9. 1. 1.3 The risk and possible complications of the proposed treatment.4.9. 1. 1.4 Advised him/her of the available alternatives, including the option of no treatment.3. 10.2 The proposed treatment, possible treatment alteration, including no treatment.3. 13.2. 1. 1.3 It must be documented in the patient's permanent record.3. 13.5. 1.5 Giving the right to accept or refuse the transfusion.4.3 Use the official informed consent forms.4.9. 1. 1.9 Document the disclosure process in the patient's medical record.4. 10. 1.3 Explain to the patient that all decisions regarding his/her treatment plan will be the responsibility of his/her treating physician.This information should include the following: 3. 10. 1 The nature of the patient's condition.3. 10.4 The consequences of no treatment.3. 13.5. 1.4 Giving the opportunity to ask questions.3. 14 The patient can agree to or refuse any procedure/treatment.4.9. 1. 1.6 To act as witness if necessary.