**Institution Name:** Directorate General of Quality Assurance Centre, MoH  

**Document Title:** Policy & Procedure of Informed Consent

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1. Purpose
To describe the process for how informed consent is obtained

2. Scope
National wide

3. Definitions

3.1 Consent: Authorization for treatment or care given by the patient to a health care provider.

3.2 Informed consent: Is a process in which the physician/procedure list provides adequate information for the patient or patient's legal representative to make an informed decision on the proposed treatment or procedure.

3.3 Proceduralist: Staff who is authorized (Privileged) to perform the treatment /procedure

3.4 Competent: The patient must be oriented to time, place, person, and understand the potential risks/benefits of the proposed procedure.

3.5 Emergency Situation: A medical condition manifesting itself by acute symptoms of sufficient severity such that the absence of immediate medical attention expected to result in:

   3.5.1 placing the health of the individual in serious jeopardy,
   3.5.2 serious impairment of body functions, or
   3.5.3 Serious dysfunction of a body organ.

4. Policy
4.1 All patients have the right to make decisions regarding their healthcare and to be provided sufficient information in order to make informed decisions. (Oman National Patient Rights & Responsibilities Declaration – phrase 4).
4.2 It is the policy of Ministry of Health that the patient must be given the opportunity to give an “Informed Consent” prior to the administration of anesthesia by an anesthesiologist and prior to the performance of operative and/or invasive procedures, or situations when it is deemed advisable to have formal documentation of the patient’s consent for treatment.

5. Procedure:

5.1 Elements of Informed Consent

5.1.1 Specifically, the physician/proceduralist must convey all significant medical information that is relevant to making an informed decision by the patient.

5.1.2 This information should include all of the following:

A. The nature of the patient’s condition;
B. The proposed treatment, possible treatment alternatives, including no treatment;
C. The benefits, as well as frequently occurring and significant risks of the proposed treatment and alternatives;
D. If applicable, the possible use in education and/or research of blood or tissue removed from the patient not needed for further medical care.
E. The individuals who will be providing treatment and the role of everyone in providing the proposed treatment.
F. The patient or patient’s legal representative should be given the opportunity to ask questions and receive additional information as requested.

5.2 Documentation

5.2.1 Ministry of Health approved forms are completed on all cases.
5.2.2 If preoperative medication (sedation or pain medication) is to be administered, informed consent or verification of informed consent must be obtained prior to the administration of such medication.

5.2.3 Informed consent documentation should not include any abbreviations.

5.3 **Obtaining Informed Consent**

5.3.1 It is the treating physician’s responsibility to obtain the informed consent.

5.3.2 Only the physician/proceduralist and/or anesthesiologist can provide the information; other staff cannot be involved in providing information for informed consent.

5.3.3 Informed consent is discussed with the patient by the physician; with verbal discussion and/or supplemented through written additions that give further information relevant to the patient’s condition.

5.3.4 Age to give consent is **18 years** provided that at the time of giving consent, the patient is competent to understand the nature and purpose of the procedure or operation proposed, and the risks involved.

5.3.5 If the person cannot sign his/her name; then a thumb mark is acceptable documentation for agreement.

5.3.6 The nurse witnessing the process of informed consent signs as a witness.

5.3.7 If a translator is used in the process, the translator signs in the area designated for him.

5.4 **Exceptions**

5.4.1 Certain recognized exceptions to informed consent include:

**A. Emergency Situation**

A procedure which require informed consent may be performed without obtaining prior informed consent in an emergency, when
the patient is incapacitated and cannot make an informed decision; two physicians from the same specialty sign the consent.

B. Patient's Lack of Capacity to Consent

Patient is incapable or lacks the capacity to give a consent. In these cases, suitable alternative processes, including use of legal guardian and surrogate.

C. Minor.

If the patient is under eighteen years of age, consent should be obtained and documented from the minor's parent or the minor's legal guardian. 5.4.2 The specific facts and reasons for the exception should be documented in the medical record.

5.5 Duration of the Informed Consent

5.5.1 Informed consent may be considered to have continuing force and effect for a maximum 90 days unless the patient revokes the consent, or until circumstances change so as to materially affect the nature of, or the risks or benefits of, the procedure and/or the alternatives to the procedure to which the patient consented.

5.5.2 Revocation - A patient may revoke consent verbally or in writing. This should be communicated to the patient's physician and documented in the medical record.

5.6 Informed Consent for Continuing Therapy

Informed consent is obtained before each new procedure. However, patients in certain therapeutic programs involving a course of multiple treatments may consent to an entire course of routine therapy prior to the first treatment, and a single consent form may be signed for the entire course of treatment (not to exceed one
year), if:

5.6.1 The entire course of treatment is disclosed, consented to, and documented in accordance with this policy.

5.6.2 No material change occurs in:

A. The risks, benefits of and alternatives to the treatment;
   i. The mode of treatment;
   ii. The patient's medical condition; or
   iii. The patient's capacity to consent; and

B. Patient does not revoke consent; and Consent is re-obtained and re-documented at least annually.

C. Examples of therapeutic programs covered by this exception include repetitive blood or blood products transfusions and haemodialysis.

6. Responsibility

6.1 The treating physician or proceduralist: Disclose all information relevant to the patient's decision and obtain the patient's informed consent.

6.2 The nurse involved in the patient's care

6.2.1 Verify with the patient and/or by specific documentation of informed consent in the medical record that consent has been obtained by the physician/proceduralist prior to the procedure or treatment.

6.2.2 In the event the nurse determines that informed consent has not been obtained or documented, the nurse will contact the physician who will complete the consent process, speak with the patient, and/or provide specific documentation of the informed process which has previously taken place.
6.3 Operating/Procedure room supervisor:

6.3.1 Verifies that:

A. Consent has been obtained by the anesthesiologist and/or physician before he administers anesthesia and/or performs the procedure.

B. A witness was present during the time that the patient received the information constituting an informed consent; and when patient signed the informed consent.

6.3.2 Check for validity of the informed consent against the following criteria:

A. Information has been provided to the patient prior to the surgery or procedure;

B. Has been explained to the patient by the anesthesiologist and/or the physician;

C. The consent form have been filled in with the necessary information;

D. All signatures required have been obtained.

6.3.3 Assures that the patient has been informed and can:

A. State the name of the physician or other practitioner who has primary responsibility for the patient’s care (Oman National Patient Rights & Responsibilities Declaration – phrase 3).

B. Identify the professional status of individuals responsible for authorizing and performing treatment and procedures.

Please consider:

6.4 It is good practice to confirm with the patient prior to the procedure that he or she has not had a change of mind.

6.5 There are three key components of informed consent:

6.5.1 Competence: the patients must be capable of understanding the essential nature of their condition along with the treatment proposed, its intended benefits, risks and possible side effects;
6.5.2 Sufficient information: the patient has the information that a reasonable person in his position would expect to have;

6.5.3 Voluntary choice: the patient must be allowed to make a decision (either to accept or decline healthcare services) freely, without any form of coercion or constraint.
7. Document History and Version Control

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Dr. Khaled Alhussainy Abulmajd | Concerned Team | Minister of Health

8. Related Documents:

8.1 P&P of Patient Identification (MOH/DGQAC/004/Vers 1.0)

8.2 P&P of Safe Surgery, Preoperative Communications (MOH/DGQAC/006/Vers 1.0)

8.3 P&P of Safe Surgery, Ensure correct patient, procedure and correct site for invasive/surgical procedures (MOH/DGQAC/007/Vers 1.0)
9. References:

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<td>K.A. Abulmajd</td>
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