Malaysian Medical Council

CONSENT FOR TREATMENT OF PATIENTS
BY REGISTERED MEDICAL PRACTITIONERS

1. Definition

In general terms, CONSENT is the voluntary acquiescence by a person to the proposal of another; the act or result of reaching an accord; a concurrence of minds; actual willingness that an act or an infringement of an interest shall occur.

Consent is an act of reason and deliberation. A person who possesses and exercises sufficient mental capacity to make an intelligent decision demonstrates consent by performing an act recommended by another. Consent assumes a physical power to act and a reflective, determined, and unencumbered exertion of these powers.

Consent refers to the provision of approval or assent, particularly and especially after thoughtful consideration.

2. Necessity For Obtaining Consent

Generally, no procedure, surgery, treatment or examination may be undertaken on a patient without the consent of the patient, if he or she is a competent person. Such consent may be expressed or implied and may be verbal or in writing.

Obtaining a patient’s consent is an important component of good medical practice, and also carries specific legal requirements to do so. Except in an emergency where the need to save life is of paramount importance, the consent of the patient must be obtained before the proposed procedure, surgery, treatment or examination is undertaken. Failure to do so may result in legal action for assault and battery instituted against the medical practitioner.

3. Necessity To Warn Patients About Material Risks

Every patient as an individual has a choice whether or not to undergo a proposed procedure, surgery, treatment or examination.

A medical practitioner is obliged to disclose information to the patient and to warn the patient of material risks before taking consent is. Failure to obtain a patient’s consent or disclose material risks may be interpreted as a failure of the standard of care resulting in a disciplinary inquiry by the Medical Council or may even be construed as a breach of duty of care and legal action instituted.
While a patient might consent to a procedure after being informed in broad terms of the nature of the procedure, this consent will not amount to an exercise of choice unless it is made on the basis of relevant information and advice.

The medical practitioner must inform the patient, in a manner that the patient can understand, about the condition, investigation options, treatment options, benefits, all material risks, possible adverse effects or complications, the residual effects, if any, and the likely result if treatment is not undertaken, to enable the patient to make his own decision whether to undergo the proposed procedure, surgery, treatment or examination.

4. **Explanatory Notes/Documents**

It is recommended that practitioners provide additional information on risks and adverse effects of any procedure in a written explanatory document which the patient (or next-of-kin or legal guardian) can read, request further explanation where necessary, understand and append a signature to that effect.

These Explanatory Notes will be considered an annexure to the main consent form signed by the patient or next-of-kin or legal guardian.

Where such explanatory notes or document are not available or not in standard use, the practitioner may note down the risks and adverse effects, as explained to the patient (or next of kin or legal guardian) in the patient’s case notes and duly signed initialled by him, with the date.

5. **Circumstances in Which Consent May Not Be Required**

There are several exceptions to the rule that the consent of a patient must be obtained before commencing any procedure, surgery, treatment or examination, and they include the following:

A medical emergency is defined as an injury or illness that is acute and poses an immediate risk to a person's life or long term health. Consent is not required in emergencies where immediate treatment is necessary to save an adult person's life or to prevent serious injury to an adult person's immediate and long term health where the person is unable to consent, subject to there being no unequivocal written direction by the patient to the contrary, or where there is no relative or any legal guardian available or contactable during the critical period to give consent.

In such circumstances, a consensus of the primary surgeon (who is managing the patient) and another registered practitioner is obtained and the surgeon signs a statement stating that the delay is likely to endanger the life of the patient. The registered medical practitioner must co-sign the consent form.

Specific arrangements apply for the obtaining of consent from a third party such as a parent or guardian of a child patient (see infra, Part 6 et seq.).

Consent of the patient may not be required for any treatment that may be ordered by a court of law, for example, an order for the specific treatment of a minor, or a patient on life-support.
6. Patients Who Are Young Persons (Minors)

The Laws of Malaysia Act 21: Age of Maturity Act 1971 states under Age of majority: “The minority of all males and females shall cease and determine within Malaysia at the age of eighteen years and every such male and female attaining that age shall be of the age of majority”

Generally, whether a young person is sufficiently mature to provide a valid consent to medical treatment depends not only on his or her age but also on whether he or she has sufficient maturity and intelligence to understand the nature and implications of the proposed procedure, surgery, treatment or examination. This must be decided on a case-by-case basis, and whatever decisions made must be “in the best interest of the patient”.

It is important to note that for the purposes of the Regulations, a patient who is unmarried and below 18 years of age does not have the capacity to give valid consent to any medical procedure or surgery.

If a minor presents with an adult other than a parent, the attending medical practitioner should attempt to ascertain the adult’s relationship to the child and whether the adult is the child’s guardian. Where the adult does not appear to be the child’s guardian, but bears some relationship to the child, and confirms that the parent/guardian is aware that he/she is accompanying the child, it is reasonable to assume that the parent or guardian has delegated responsibility to that person, unless there is any indication to the contrary (i.e. a previous objection by the parent to that person exercising any authority in relation to the child).

Where the patient is an “infant” as defined under the Guardianship of Infants Act 1961, it would be prudent for the medical practitioner to consult or obtain the consent of the infant’s legal guardian. Under the Guardianship of Infants Act 1961, the guardian of the person of an infant shall have the custody of the infant, and shall be responsible for his support, health and education.

The Law Reform (Marriage & Divorce) Act 1976 makes it clear that each parent has full responsibility for each of his/her children who is under 18 years of age. Parental responsibility is not affected by changes to relationships (i.e. if the parents separate). Each parent has the responsibility for his/her child’s welfare, unless there is an agreement or a Court has made an order to the contrary.

This means that the consent of either parent to his/her child’s medical treatment is usually sufficient. There are two circumstances where the consent of either parent may not be sufficient:

i. Where no formal court orders have been made, and one parent consents and the other refuses. The best way of handling this situation is by counselling the parents and trying to reach agreement on what is in the child’s best interests.

ii. Where a Court of law has made an order to the contrary.

In recognising the evolving capacity of the child, the United Nations Convention on the Rights of the Child (commonly abbreviated as the CRC, CROC, or UNCRC) as a human rights treaty setting out the civil, political, economic, social, health and cultural rights of children, defines a child as any human being under the age of eighteen, unless the age of majority is attained earlier under a state’s own domestic legislation.
7. Patients Who Are Incapable Of, or Impaired With, Decision-Making Ability

Impairments to reasoning and judgment which may make it impossible for someone to give informed or valid consent include such factors as basic intellectual or emotional immaturity, high levels of stress such as Post Traumatic Stress Disorder (PTSD) or as severe mental retardation, severe mental illness, intoxication, severe sleep deprivation, Alzheimer's disease, or being in a coma.

In such circumstances, and in an emergency to save life, the procedure as outlined for emergency treatment or management should be followed.

When there is a relative, next-of-kin or legal guardian is available, the consent may be obtained from such a person if an elective or non-emergency operation is necessary from a medical practitioner’s considered opinion.

Under the Mental Health Act 2001, consent is generally not required for conventional treatment apart from surgery, electroconvulsive therapy or clinical trials for patients with mental disorder as defined by the said Act.

In instances where consent is required it must first be obtained from:

i. The patient himself if he is capable of giving consent as assessed by a psychiatrist; or

ii. If the patient is incapable of giving consent, from his guardian in the case of a minor or a relative in the case of an adult, “guardian” and “relative” as defined in the Mental Health Act;

iii. Two psychiatrists, one of whom shall be the primary or attending psychiatrist, if the guardian or relative of the patient is unavailable or untraceable and when the patient himself is incapable of giving consent.

8. Types of Consent

In all instances or episodes of taking consent, whenever possible conducted in privacy, it must be ensured that the patient (or next-of-kin or legal guardian) is fully aware of the objective and process of giving consent, be comfortable and composed.

a. **Implied consent** is a form of consent which is not expressly granted by a person, but rather inferred from a person's actions and the facts and circumstances of a particular situation (or, in some cases, by a person's silence or inaction). This may become an issue if there is any dissent or disagreement arising from the patient’s interpretation of the practitioner’s actions or the outcome thereof.

b. **Expressed consent** may be in oral, nonverbal or written form and is clearly and unmistakably stated. Issues may arise when the consent is through oral communication, as stated under ‘implied consent’.

c. **Informed consent** can be said to have been given based upon a clear appreciation and understanding of the facts, implications, and future consequences of an action. In order to give informed consent, the person concerned must have adequate reasoning capacity and
be in possession of all relevant facts at the time consent is given. This term was first used in a 1957 medical malpractice case by Paul G. Gebhard in the USA.\textsuperscript{6,7}

Informed consent is a medico legal requirement or procedure to ensure that a patient knows all of the risks and costs involved in a treatment. The elements of informed consents include informing the patient of the nature of the proposed procedure, surgery, treatment or examination, possible alternative treatments, and the potential risks and benefits of the treatment.

d. Valid consent

Valid consent can be defined as the voluntary agreement by an individual to a proposed procedure, given after appropriate and reliable information about the procedure, including the potential risks and benefits, has been conveyed to the individual.

It is generally accepted that consent to be “valid” should be “informed”; the requirements for obtaining valid consent are:

i. It must be given by a person with legal capacity, and of sufficient intellectual capacity to understand the implications of undergoing the proposed procedure.

ii. It must be taken in a language which the person understands.

iii. It must be given freely and voluntarily, and not coerced or induced by fraud or deceit.

iv. It must cover the procedure to be undertaken.

v. The person must have an awareness and understanding of the proposed procedure and its known or potential risks.

vi. The person must be given alternate options to the proposed treatment or procedure.

vii. The person must have sufficient opportunity to seek further details or explanations about the proposed treatment or procedure.

viii. There must be a witness/interpreter, who may be another registered medical practitioner or a nurse, who is not directly involved in the management of the patient nor related to the patient or the medical practitioner, or any such person who can speak the language of the patient, to attest to the process during taking of the consent.

e. Verbal consent is given by using verbal communication, and may be open to debate and as far as possible, should be avoided.

f. Nonverbal consent is given by using nonverbal communication, like nodding acquiescence or extending the arm for a procedure, which are also open to debate and should be avoided.

9. Written Consent

The Private Healthcare Facilities and Services (Private Hospitals and Other Private Healthcare Facilities) Regulations 2006 states in Part VIII Consent under section 47 (3) “Consent obtained or caused to be obtained under this regulation shall be in writing.”\textsuperscript{8}
Without prejudice to the above, which relates to practice in private healthcare facilities and services, written consent when not taken in a standard consent form, should nevertheless be recorded in the patient’s case notes/record that the patient had been informed and had consented to a particular stated procedure like setting up an IV line or giving rectal enema. This is to safeguard against any unexpected outcome.

10. Pre-requisites for Medical Practitioner Taking Consent

There are a few pre-requisites for the taking of consent by a practitioner from a patient (or the next of kin, or legal guardian as the case may be):

a. The doctor and the patient must have met or know each other in the context of doctor-patient professional relationship.
b. The doctor who is planning to operate or do an invasive procedure on a patient must establish personal contact with the patient, in other words the two must meet before the intended procedure.
c. The doctor must explain to the patient the nature of the procedure and its objective, and alternative procedures.
d. The doctor must explain possible complications, which may delay or affect the result of the procedure, as well as influence the duration of stay in the ward.

These pre-requisites are best satisfied when the person who is planning to perform the procedure personally and directly takes the consent from the patient. This would establish and uphold the tenets of good medical practice and pave the way for an accepted standard and quality of professional care.

11. Responsibility of Medical Practitioner Taking Consent

It is understood that by a particular practitioner undertaking the procedure he is competent, skilled and experienced (in the broadest senses of the words). Such an assurance is assumed to be so by the patient.

It is generally required that only fully registered medical practitioners may take consent for a procedure, surgery, treatment or examination from a patient, and also perform the procedure, surgery, treatment or examination for which that consent has been taken.

The primary responsibility and vicarious liability in the event of complaints rests on the practitioner who has taken the consent and who additionally has himself performed the procedure, surgery, treatment or examination. This is based on the requirement that the practitioner taking the consent and performing the procedure, surgery, treatment or examination will be able to explain to the patient all details of the proposed procedures as above, which would include possible unexpected findings and complications, and the remedial actions that will be taken.

In the event of the practitioner taking the consent and the practitioner performing the procedure, being two different registered medical practitioners, the final responsibility and liability will be on the practitioner who performs the procedure, who should, before performing the procedure,
confirm the nature of the information given to the patient by the other practitioner in the course of taking the consent.

In a department with many practitioners of varying competence, skill and experience, the ultimate and direct responsibility rests upon the Head of Department for having allowed a junior practitioner (including trainees, medical officers and housemen as part of their training) to take consent and perform a specific procedure as described above, or for having delegated a specialist to make such decisions on his behalf.

It is not enough for the Head of that department to assume or to claim that a particular practitioner has the competence, skill and experience to perform a procedure, surgery, treatment or examination independently and without supervised assistance unless the Head of Department himself is so aware and convinced, and has reason to believe it to be so.

12. Standard Consent Form

A consent form is routinely being used by healthcare facilities and services in the country and contains various details.

A standard consent form should contain:

a. Patient identification data: Name, IC Number, Address, gender
b. Name of procedure/surgery to be performed in full
c. Type of anaesthesia
d. Name(s) of registered medical practitioner(s) performing the procedure/surgery.
e. Permission to proceed with any additional procedure that may become necessary during the surgery and related to the procedure for which the original consent had been obtained.
f. A statement to the effect that the person who is performing the procedure has explained to the patient (or next-of-kin) the nature of the procedure and the potential material risks.
g. A statement to indicate that the Patient has received and read additional Explanatory Notes, if so provided by the practitioner.
h. Signature of Patient/next-of-kin (relationship) and IC Number and date
i. Signature of Practitioner and name stamp, and date
j. Signature & name of Witness (to the signing of the form) and date.

13. Prepared Material with Information about a Treatment

Prepared material such as brochures or standard forms (with translations where relevant) with information about a procedure, surgery, treatment or examination may be useful if given to the patient as a means of stimulating discussion and for guiding the medical practitioner when informing the patient about a proposed procedure, surgery or treatment.

However pre-prepared material should not be used as a substitute for informing or making sure that a patient understands the nature of, and risks involved in, the procedure, surgery or treatment, as the provision of such material per se will not necessarily discharge the medical practitioner from his legal duty.
The medical practitioner should assist the patient to understand the material provided and, if required, explain to the patient any information that he or she finds unclear or does not understand. The medical practitioner must afford the patient the opportunity to read the material and raise any specific issues of concern either at the time the information is given to the patient or subsequently.

The medical practitioner must ensure that any pre-prepared material given to the patient is current, accurate and relevant to the patient.

If such pre-prepared information material does not disclose all “material risks” either in general terms or otherwise, the medical practitioner must provide supplementary information on such “material risks” as are not disclosed, verbally. The likelier the risk, the more specific the details should be.

An inadequate or inaccurate information sheet may have significant negative implications in subsequent litigation. It may give rise to an inference that the patient was not properly informed or ill-informed. In most cases in determining what "material risks" should be disclosed, an information sheet cannot be a substitute for a full and frank discussion with the patient.

Any additional information provided should be specifically noted on the information sheet or in the medical practitioner’s case notes.

[Explanatory notes and documents prepared by the practitioner in Section 4 do not come under this category].

14. **Faxed or Photocopy Of Consent Form**

It is necessary for the patient, or next-of-kin or legal guardian to be physically present before a registered medical practitioner for purposes of giving consent for a procedure, surgery, treatment or examination. Such presence will provide the practitioner the opportunity to personally and directly explain the procedure to be undertaken as described above.

For the above specific reasons, faxed or photocopied consent form is not acceptable.

15. **Additional Special Aspects on Consent**

   a. **Period of validity of consent**

      It is generally believed that for an acceptable standard of care, the consent for an invasive procedure has to be taken a reasonable period before the procedure. A reasonable period would be not more than 24 hours. If during this period there is a change in the circumstances or condition of the patient requiring a review of the procedure initially planned, for which consent had been taken, then it is incumbent on the practitioner to obtain a fresh consent.

      For any procedure not carried out within the 24 hours, or delayed for any period thereafter, for whatever reason, including requiring an in-patient to be discharged home, a new consent has to be taken before undertaking the procedure, surgery, treatment or
examination as the circumstances or the disease condition may have changed during that period or the patient may have forgotten the details of the consent.

It sometimes is the practice of convenience in many healthcare facilities that consent is taken when the patient is being seen in the clinic by the practitioner, and while scheduling the intervention, which may be in a week's time or later. In such instances, when the patient is seen on admission at the time before the surgery, it is best to remind him/her about the proposed procedure, surgery, treatment or examination and salient points in the consent form previously signed by the patient. Nothing should be taken for granted.

b. **Chronic conditions requiring periodic treatment, including transfusion of blood or blood products**

Good standard of care requires that consent has to be specific in time and procedure for any invasive treatment. For example, for a patient requiring de-sloughing or related procedure (like digital ablative surgery) of a diabetic ulcer or a haemophiliac patient requiring periodic blood transfusion or chemotherapy, consent has to be taken on every occasion that the procedure is to be undertaken.

c. **Consent for photographs and audio-visual recordings**

Prior consent must be obtained if the practitioner is planning to take clinical photographs or to make audio-visual recordings before, during or after an invasive procedure. There may be medico-legal reasons for taking photographs, or audio-visual recordings, as in cosmetic surgery or ablative surgery involving upper or lower limbs. Such photographs and audio-visual recordings rightfully belong to the patient and if to be retained by the practitioner, further consent must be obtained. If such photographs or audio-visual recordings are requested by the patient to be taken away, it is necessary to keep copies of such material in the patient’s records, for future requirements, like medical reports. This information are available in the MMC Guideline on Audio and visual recordings in Medical Practice.

d. **Consent on admission**

Based on the principles that consent must be specific for a procedure, “blanket” consent on admission of a patient, either as an out-patient or in-patient, is not allowed. The reason that this will cover all treatments, including those which may be perceived to be minor, like giving injections or per vaginal examination, and which may be considered “implied”, is not acceptable. Similarly, consent for release of information and details on diagnosis of diseases and/or management, to employers or third party payers (Managed Care Organizations or insurance firms) has to be specific and contemporaneous, and not “blanket” at time of commencement of employment. Similarly, too, consent for the release of results and/or reports on pre-employment medical examination to the prospective employer has to be obtained from the applicant.

e. **Consent for Investigations for HIV**

Because of the special implications to persons who may test positive for HIV, and the need for counselling and further management, specific consent has to be taken before the tests are carried out.
f. Consent for keeping (for teaching purposes) organs or tissues removed at surgery

Patients may request for specimens removed at surgery (limbs, spleen, gall bladder, etc.) to be ritually disposed and this should be complied with. In instances where such a request is not made, the surgeon may seek the consent of the patient or next-of-kin to retain the specimens for medical education or research purposes, but without having to reveal the identity of the patient. Under section 2 of the Human Tissues Act 1974, where the deceased during his lifetime has, either in writing or verbally in the presence of two or more witnesses during his last illness, expressed a request that his body or a specified tissue in his body be used after his death for therapeutic purposes, or for purposes of medical education or research, the person lawfully in possession of his body after his death may authorize the use of the deceased’s body or removal of the organs, unless he has reason to believe that the request was withdrawn.  

10. Consent for sterilisation and hysterectomy

Sterilisation procedures in a woman or man should be consented by the patient. Similarly, hysterectomy and orchidectomy should also normally involve consent by the patient.

h. Consent for release of patient data to another practitioner for treatment

Written consent must be given by a patient who is being transferred to another healthcare facility or medical practitioner for purposes of further treatment, for release of relevant parts of his medical records.

16. Refusal to Give Consent for Treatment

Generally, every individual is entitled to refuse medical treatment. A legally competent person has a right to choose what occurs with respect to his or her own person. For such persons, the right to refuse treatment exists, regardless of the reasons for making the choice whether they are rational, irrational, unknown or even non-existent. Forcing medical treatment on a competent patient who has validly refused such treatment could be tantamount to an assault or battery.

However, if the patient's circumstances change significantly, any prior refusal of medical treatment may not remain valid and may need to be reviewed with the patient.

Similar to consent to treatment, refusal of treatment may be expressed or implied and may be in writing or given verbally. The refusal of treatment by a patient should also be recorded in detail and in writing in the medical record or the medical practitioner’s case notes, and where possible, signed and dated by the patient.

17. Advance Care Directives (or Living Wills)

A medical practitioner should refrain from providing treatment or performing any procedure where there is an unequivocal written directive by the patient that such treatment or procedure is not to be provided in the circumstances which now apply to the patient (“Advance Care Directive”).
However, this does not apply where the patient’s directive contains instructions for illegal activities, such as euthanasia or the termination of pregnancy.

Should there be an Advance Care Directive, the medical practitioner should consider whether it is sufficiently clear and specific to apply to the clinical circumstances which have arisen. The medical practitioner should also consider the currency of the directive, whether it can be said to be made in contemplation of the current circumstances (for example, whether the directive was made before or after the diagnosis of the current illness). Whether there is any reason to doubt the patient’s competence at the time that the directive was made, or whether there was any undue pressure on the patient to make the directive, are factors that should be considered.

In an emergency, the medical practitioner can treat the patient in accordance with his or her professional judgment of the patient’s best interests, until legal advice can be obtained on the validity or ambit of any Advance Care Directive that may have been given by the patient. Where there are concerns about the validity or ambit of an Advance Care Directive in a non-emergency situation, the medical practitioner should consult the patient’s spouse or next of kin and the medical practitioner should also consider the need to seek legal advice and to discuss the issue with his or her colleagues, or other clinicians involved in the patient’s care. Such discussions should be documented in the patient’s medical case notes.

18. Consent for Other Procedures

Aspects of consent are also covered in MMC Guidelines on Assisted Reproduction, Organ Transplantation and Clinical Trials & Biomedical Research, Confidentiality, Good Medical Practice and Release of Medical Records and Reports, Audio and Visual Recordings in Medical Practice.

References:


Adopted by the Malaysian Medical Council on 15 January 2013
Notes:

a. The initial draft was prepared by the MMC Committee chaired by Datuk Dr. Mahmud Mohd Nor, with Mr. Darryl S.C. Goon, Dr. Eeson Sinthamoney, Dato’ Dr. Abu Hassan Asaari, Dr. (Mr.) Zulkiflee Osman, Dr. (Mr.) Zainal Ariffin Azizi, Dr. Lim Wee Leong, Dr. David Quek Kwang Leng, Mdm. Narkunavathy Sundaresan, Mr. Donald Joseph Franklin, Mr. Mohamad Fazin Bin Mahmud, Dr. Rosnah Binti Yahya and Dr. Nor Akma Binti Yusuf as members and submitted to the Council on 9 November 2010.

b. In view of various comments about the initial report by members of the Council, Dato’ Dr. Abdul Hamid Abdul Kadir, Chairman of the MMC Ethics Committee was appointed to review the report.

c. The sentiments expressed by those present at a meeting convened to discuss the major issues in consent taking, held on 10 January 2012, have also been taken into consideration in the preparation of this draft, as well as at meetings of the MMC in March 2012 and few times at subsequent Council meetings.

d. Amendments to the draft suggested by some members of the Malaysian Medical Council (Dato Dr Megat Burhainudin bin Megat Abdul Rahman, Professor TA Lim, Professor Dr Zainul Rashid Mohd Razi and Dr Milton Lum), at various times, were considered at a meeting on 7 December 2012, at which were present Dato Dr Megat Burhainudin bin Megat Abdul Rahman, Professor TA Lim and Dr Milton Lum.

e. This draft on Consent in Medical Practice covers in great detail one section in the Code of Professional Conduct. Aspects of Consent are also covered in MMC Guidelines on Confidentiality, Good Medical Practice, Release of Medical Records and Reports, Assisted Reproduction, Organ Transplantation, Clinical Trials and Biomedical Research, Audio and Visual Recordings in Medical Practice.