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	<b>Ethical Policy On Informed Consent</b>		Issue Date:	
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### 1.0 Purpose

This policy shall provide guidelines to describe the CLMMRH hospital ethics policy on informed consent.

### 2.0 Scope


This Hospital Ethics policy on Informed Consent is to provide guidelines to Medical Doctors, nurses, patients regarding information to be given to patients, consent procedures, who can sign consent and content of the Inform Consent Form (ICF) and obtaining consent.

### 3.0 References


N/A

### 4.0 Definition of Terms

Terms	Definition
Bioethics	Is the study of moral issues in the fields of biology and health. It is a field of self-investigation and enlightened self-interest, and it therefore provides a foundation for a meaningful human life.
Informed Consent	It is a written document/ process of getting consent by giving information, signed by the patient and/or relative stipulating that he/she has been given sufficient information regarding a procedure or treatment.
Mental Competence	Is not a legal concept. However, courts declare a person as mentally incompetent on the basis of the evaluation conducted by appropriate medical fields such as the psychiatrist or psychologist. The courts are not expert nor trained to assess the mental competence of a person.
Mental Capacity	Is the clinical concept of understanding. Its standard varies according to the extent of ability to deliberate the probability of risk or benefits and whether the patient consents or refuses.
Substituted Judgment	A decision made by a surrogate decision maker in cases where the patient had prior mental capacity and now is mentally incapacitated but whose decision are known or can be known.

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Best Interest	Is the standard of substituted judgment when the decision of the patient is not known or could not be made known.
Advance Directives	Legal documents that contain instructions on medical care in case of incapacitation.
Natural Death Acts	Affirms a person's right to make decisions regarding terminal care and provide directions on how it is to be affected after loss of decision making. It may include withholding/ withdrawing treatment /care that lead to natural death.
Hospice Care	Patient centered holistic care focusing on quality of life and extending support to family and care providers.
Palliative Care	Is total active care of patients whose disease is not responsive to curative treatment to achieve the best quality of life until they die. It includes the control of pain and other symptoms, psychological, social and spiritual support for the patient and the family. It may be initiated early in the course of the disease.
Durable Power of Attorney	In health care, it authorizes the patient to name the person (s) who shall be the surrogate decision maker for the patient.
Living Will	An informal document that instructs the physician on acceptable or unacceptable modes of terminal care.
Competent Refusal	Refers to refusal of treatment, refusal based on unusual belief, enigmatic refusal or refusal of information.
Medical Futility	Is the decision to forgo medical intervention when the intervention is incapable of achieving the desired goals in moribund patients who are terminally ill, When prolongation of treatment will not reverse the course of the disease but merely postpone death causing superfluous pain and suffering to the patient.
Proportionate Care	When the intervention is not too burdensome to the patient in relation to the benefits involved, it should offer reasonable hope of benefit that can be obtained without excessive expense, pain or inconveniences.
Euthanasia	Deliberate action with the intention of killing the patient at his/ her request.


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## 5.0 Responsibility


Designate	Responsibilities
Hospital Ethics Committee	When there is doubt as to the patient's capacity to give consent the HEC can be called upon to determine competence and capacity to give consent.
Medical Doctors	Obtain consent from patients and determine their capacity to give consent.

## 6.0 Policies

- 6.1 Patients are admitted and treated at CLMMRH regardless of race, creed, religion or political affiliations.
- 6.2 It is the policy of CLMMRH to provide sufficient information to patients and/or relatives to allow making decisions regarding their health care. Patient's consent shall be obtained for admission and every diagnostic procedure, including anesthesia, before it is started or given.
- 6.3 The attending physician performing such procedure or treatment has the following duties:
  - a. The patient and/or relatives are fully informed regarding the risks / benefits and options.
  - b. The informed consent has been duly signed before proceeding with the contemplated procedure or treatment. In case of anesthesia procedures, the anesthesiologist will be responsible for obtaining consent. Additional consent needs to be obtained for additional procedures that need to be done over and above what the patient initially consented for by the surgeon himself.
- 6.4 Patients of legal age, of sound mind, and are conscious shall sign the consent. Legal age shall mean at least 18 years old.
- 6.5 In case of unconscious or are mentally incapacitated patients, minor children(newborn to 17 years and 364days), the consent shall be signed by any of the following who are present, in order of priority:
  - 6.5.1 Legal Spouse (for married patients)

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- 6.5.2 Parent – father or mother
- 6.5.3 Grandparent – paternal or maternal
- 6.5.4 Eldest brother or sister – provided they are of legal age
- 6.5.5 Eldest son or daughter – of legal age
- 6.5.6 Legally appointed guardian
- 6.6 For married patients, when the reproductive capacity is at stake; spousal consent and signature of the spouse is not necessary under the following conditions:
  - 6.6.1 The couple has discussed the form of family planning they will use.
  - 6.6.2 The couple and the attending physician have discussed the form of family planning they will use.
  - 6.6.3 If the woman has a medical condition that requires bilateral tubal ligation (BTL), she can sign for herself.
  - 6.6.4 In emergency cases, where the husband is not around, the woman can sign for herself.
- 6.7 Such consent shall be signed by a witness present during the signing.
- 6.8 The consent form shall contain the following:
  - 6.8.1 Date and time it was signed.
  - 6.8.2 Name and nature of the proposed procedure or treatment.
  - 6.8.3 A statement that the patient or anyone signing has been properly informed regarding the procedure or treatment with its risk, benefits and options and that the signatory has fully understood it.
  - 6.8.4 Full name of the signatory/ies below the signature/s.
  - 6.8.5 Relationship of the signatory to patient.

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6.8.6 Complete address and contact details of the signatory.

6.8.7 Name and signature of (1) witness to the signing.

6.9 In cases of patient refusal to undergo suggested treatment or procedure, their reason for refusal is asked and alternative options given. If the patient wishes to go home against medical advice, a waiver shall be signed by any of the signatories as enumerated above (section 6.5). However, for as long as patient remains in the hospital, the hospital provides care until a transfer or discharge is made. A referral to social welfare services may be made to elucidate the refusal for treatment and to facilitate transfer and or discharge of the patient.


6.10 In emergency cases, when no one can sign the consent (see section 6.5) and in the opinion of the attending physician even a slight delay caused by waiting for consent may jeopardize the life of the patient, the physician can sign the consent in behalf of the patient (implied consent) and proceed with the procedure or treatment. It is the medical doctor's responsibility to explain to the patient or relatives later.

6.11 Physicians are encouraged to limit the procedure to what is stipulated in the consent form. Should the need arise to extend the surgery beyond what is in the consent, attempts shall be made to secure consent for such additional procedure. If relatives are not around to sign the consent, the physician can sign for the patient (implied consent) and is responsible for securing consent after the procedure and give the reason for the additional procedure.

## 7.0 Provision of amendment

This policy shall be amended anytime whenever necessary.

<b>Prepared by/Date:</b>	<b>Approved by/Date:</b>
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