

CONSENT FORMS NEWSLETTER

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PROVISIONS FOR CONSENT UNDER LAW

Sections 87 to 91 of Indian penal code deals with consent. Section 88 of IPC lays down that an act is not offence if it is not intended or not known to be likely to cause death, which causes any harm to a person from whose benefit it is done in good faith with his consent to suffer it. Thus after a valid consent if surgeon operates on patient and patient dies on the operation table, then the surgeon cannot be held guilty of murder. Persons who are non-qualified in medical profession are not allowed to take the plea of this section, as they are not said to do the act in good faith. IPC 52 says that an act is only done in good faith if it is done with due care and attention. Section 91 of IPC serves as a corollary to sections 87 to 89. It states that the exceptions contained in sect 87 to 89 do not

WEBSITE UPDATION

In the broadest sense, medical negligence (or clinical negligence) is when a medical professional or medical institute is in breach of the legal duty of care it owes to an individual – the patient. Medical negligence can be almost anything where an individual or a process has resulted in a patient coming to harm.

extend to acts, which are offences independently of any harm, which they may cause to the person, giving consent. Thus causing miscarriage (unless caused in good faith for the purpose of saving the life of the women) is an offence independently of any harm which it may cause or be intended to cause to the women and the consent of the women or of her guardian for causing such miscarriage does not justify the act (91 IPC)4.

Barring physical examination, any medical procedure requires written consent. Written consent should refer to one specific procedure and not blanket permission on admission to hospital. It is on the safest side to take the consent of a spouse if the operation destroys or limits sexual function. While not legally necessary it is good medical practice to consult with relatives of patient in patient's best interest and ones this has been established

then doctor can continue to give treatment in good faith. Consultation, consent and clinical confidence will never put the doctor in any tort fessors cases. Prisoners and persons released on bail can be treated without their consent in the interest of justice of society. A registered medical practitioner can examine an accused by using reasonable force if the examination is requested by the investigating police officer not below the rank of police sub inspector (CrPC 53).(Force should be applied by police.) Under subsection 2 of CrPC 53 which lays down that, whenever the person to be examined is female the examination shall be made only by or under the supervision of female registered medical practitioner. The obtaining of such evidence, it has been held, is not violative of article 20(3) of constitution, which grants protection against self-incrimination, it was held so by high court in Bombay vs. Kathi Kalu case⁵.

Consent of the patient cannot be defense to medical practitioner in negligence. Whole law of negligence assumes the principle of consent⁶.Not to be applicable when the act is not done with reasonable care and competence. If found under the influence of alcohol, then consent of such person will not be valid, so it is always better to obtain consent from guardian / parents.(Exception - Section 53 CrPc and Bombay prohibition act.)

HOW CONSENT SHOULD BE OBTAINED

The elements that a physician must discuss with his / her patient to fully obtain informed consent are the following:

1. The diagnosis and the nature of the condition or illness calling for medical intervention.
2. The nature and purpose of the treatment or procedure recommended.
3. The material risks and potential complications associated with the recommended Treatment / procedure.
4. All feasible alternative treatments or procedures, including the option of taking no action, with description of material risks and potential complications associated with the alternatives.
5. The relative probability of success for the treatment or procedure in understandable terms.

INGREDIENTS OF A LEGALLY VALID INFORMED CONSENT- For consent to be legally valid it must fulfil following criteria:

1. A person of sound disposing mind should give the consent.

1. The consent should be given voluntarily, without any fear, force, fraud, undue duress, coercion, misrepresentation of facts and threats of physical violence, death etc.
2. The consent needs to be free, fair, uninhibited, clear, direct and personal.
3. The consent should be well informed.
4. The consent should be taken prior to the procedure (therapeutic or diagnostic).
5. The consent should be complete and specific.
6. The consent should be given by a competent person means by a person who is of sufficient maturity to understand the nature and consequence of the act to which he has given consent.
7. A third uninterested party must witness the consent.
8. Signed by the doctor, patient (or guardian) and witnesses. Should be written in patient's own handwriting.

Section 90 of IPC defines consent in negative terms. As per this section, any consent given under the following five circumstances will not be true consent. Analysis of this section shows that consent is not true consent if it is given-

1. By a person under fear of injury or,

2. By a person who is under misconception of the facts and person who obtain consent knows or has reason to believe that or consent was given in consequence of such fear / misconception.
3. By intoxicated person or,
4. By a person who is of unsound mind or, unable to understand the nature and consequences of that to which he gives consent.
5. By a person who is below the age of 12 yrs.

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REFUSAL OF TREATMENT

The patient has a right to control his or her body. Hence any treatment without consent of the patient is actionable. Any competent adult is entitled to reject any specific treatment offered to him, even if the decision may entail risk, as serious as death, and may appear wrong in the eyes of the medical profession. This concept has been rigorously followed by the western law courts in recent times. However, in our country the interest of the state in protecting and preserving the lives and health of its citizens has also been important in some rare situations.

TYPES OF CONSENT

Medical profession in India practices following types of consents.

Implied consent is one, which is not written but legally effective. When patient comes to doctor's consulting room or hospital and waits for the doctor, implied consent is presumed. Such implied consent only goes to history taking and ordinary medical examination like inspection, palpation and auscultation; it does not cover the consent for examination of private parts of the patient or matters such as vein punctures or injections or any major intervention. If any material risk is involved the specific or expressed consent must be obtained. The above discussion, thus, shows that in certain circumstances an implied consent may not be considered as sufficient. In the case of *Male v. Hopkins*⁷ it was observed that it was not negligence of a doctor, who had the patients consent for general treatment, to prescribe a particular drug known to have side effects, without first obtaining specific consent. The observation was that it was a proper consent exercise of his discretion to prescribe a particular drug even with the

risk involved. However, negligence did not arise in his failure to carry out recommended tests for the presence of other side effects, once the prescription of the drug had commenced. A good case of implied consent came up before the National Commission⁸ where one of the witnesses had stated that once the consent for excision biopsy through thoracotomy was given, the consent for removal of the mass was implied. The Commission observed (Para 19) that the surgeon need not limit the operation to diagnostic purpose but can proceed with the same for curative purposes also.

The express or specific consent may be oral or written. An oral consent is legally valid, but it is preferred to obtain written consent for major procedures because there is risk involved that the patient, in the case of oral consent, may at later stage deny that any oral consent was given by him. If, for whatever reason, only oral consent is possible, it is appropriate to make an entry in the patient's clinical record which may be of use in future if any action is brought on this count and this entry in the clinical record may afford corroborative evidence to support the defense taken by the medical practitioner concerned. In a Tamil Nadu case⁹ it was observed that in all cases where a treatment consists of certain dangerous instruments, it is the duty of medical authority to take the consent of patient, preferably in

in writing. However, in that case an oral consent was taken and the Commission regarded this consent as proper. This shows that written consent is not an absolute necessity to defend an action for assault or battery, but a written consent would afford documentary evidence that the consent was actually obtained. The cases are not rare where the action has been brought after several years prefer the evidence of the patient if a documentary evidence of express consent is not provided.

Informed consent is an ongoing process that includes the exchange of information and development of choices. This does not say that the same should be in writing. Emphasis on informed consent has been laid in *Dr. Janki S. Kumar v. Mrs. Sarafunnisa*¹⁰ where the sterilization was done without consent. It was observed that when one speaks of consent, that should be informed consent. The person who should give consent must be aware of the risks involved and on that awareness the patient should give consent. When, as indicated, the patient was in general anesthesia neither could she understand the risks involved nor could she give consent. It may be understood that it is only in emergency that the consent may be done away. Otherwise, the consent is necessary and that to in writing. When, as indicated, the patient was in general anesthesia neither could she understand the risks involved nor could she give consent.

It may be understood that it is only in emergency that the consent may be done away. Otherwise, the consent is necessary and that to in writing. In a case *Aplarain Jayanand Rathod v. Dr. Shailesh Shah*¹¹ the operation of appendicitis was performed without written consent under the guise of removal of stitches and no explanation was given for the second operation. The State commission found that the Doctor was deficient in service and was liable for compensation. In patients who are more prone for anxiety / full disclosure in presence of malignancy or unavoidable total results the doctor should use therapeutic privilege in the interest of patient, disclose the fact to the kin rather than to the patient.

Presently in India, doctrine of informed consent is not in routine practice. This type of consent may take routes in the Indian medical practice soon, since advancement in technology and information is taking place very fast and increase consumer awareness.

WHAT PROCESS DOES LEGALMD FOLLOW

MODEL FORM OF INFORMED CONSENT

I son of aged resident of being under the treatment of (state here name of doctor/hospital/nursing home) do hereby give consent to the performance of medical /surgical /anaesthesia/ diagnostic procedure of (mention nature of procedure / treatment to be performed, etc.) upon myself/upon aged who is related to me as (mention here relationship, e.g. son, daughter, father, mother, wife, etc.).

I declare that I am more than 18 years of age. I have been informed that there are inherent risks involved in the treatment / procedure. I have signed this consent voluntarily out of my free will without any pressure and in my full senses.

Place :

Date :

SIGNATURE

Time : (To be signed by parent /guardian in case of minor)

NOTES :

1. This Consent Form should be signed BEFORE the treatment is started. These formats may be modified as per individual requirements or experiences of Hospitals / Nursing Homes.
2. These formats should be in local language and in certain cases it would be prudent to record a proper witness to signature consent.
3. Informed consent forms for various situations can be made for Nursing Homes / Hospitals. Help of lawyers may have to be taken. Detailed forms on Medical history can also be maintained. Keep all records in order and safely.
4. It is important to note that written consent should refer to one specific procedure. Obtaining a 'blanket' consent on admission does not have legal validity.

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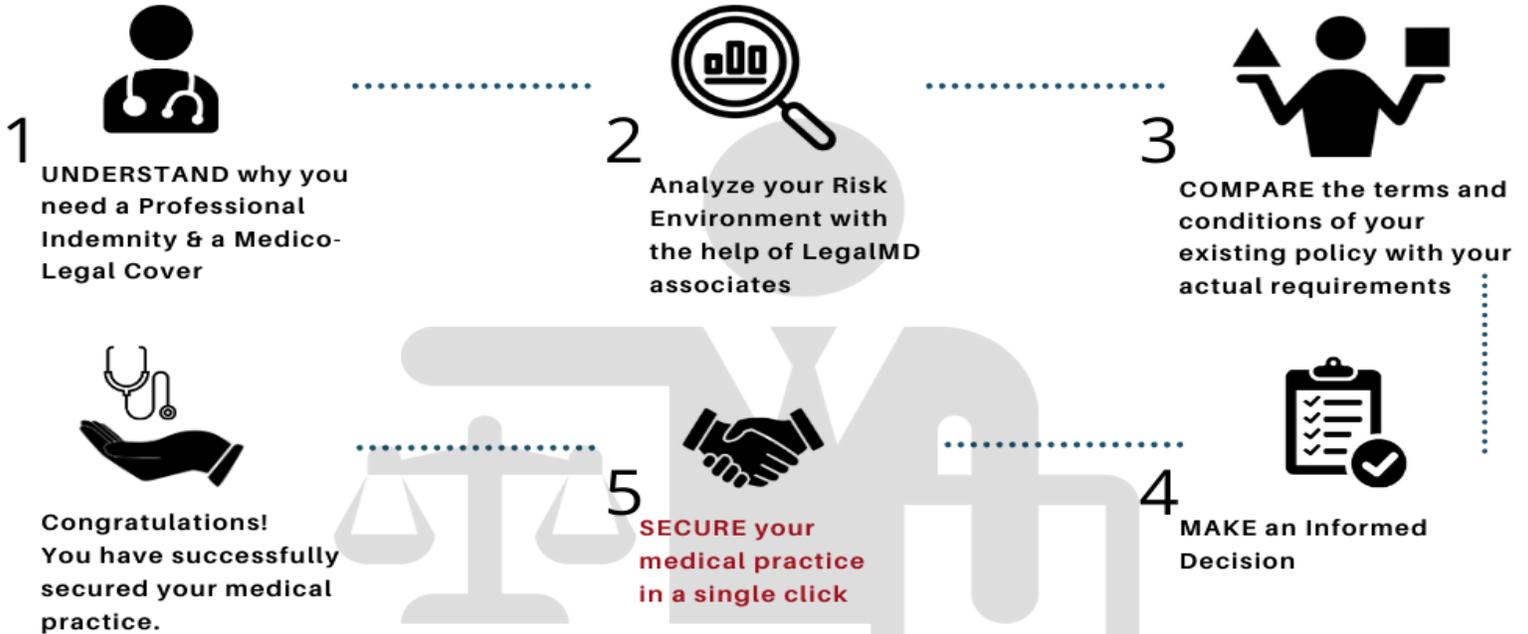
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