

# Consent form in medical practice

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Hippocrates, nearly 4 centuries before the birth of Christ, when he said "Primum non nocere" that is first do no harm perhaps can be credited with laying down the foundation of ethics in medical practice. These simple three words are laden with unfathomable weight that rests on a medical practitioner. The Hippocratic oath is regarded as a seminal document on ethics of medical practice defining good medical practice and morals. Does it have relevance today? If so why and what are the questions that a young medical practitioner would ask? The centuries have seen human beings used or misused to gain knowledge; sometimes for the betterment of the human race and sometimes just for curiosity and sometimes just because the humans were too weak to protest their abuse. The last situation is of recent times where the Nazi's had no qualms in performing in human experiments on the Prisoners of war in their captivity. The US too does not lag behind in once violating human rights. This brings us to the infamous Tuskegee syphilis experiment. The clinical study conducted between 1932 and 1972 by the U.S. Public Health Service to study the natural progression of untreated syphilis in rural African American men. The men thought they were receiving free health care from the U.S. government. They were never told they had syphilis, nor were they ever treated for it. The 40-year study was controversial for reasons related to ethical standards; primarily because researchers knowingly failed to treat patients appropriately after the 1940s validation of penicillin as an effective cure for the disease they were studying. Revelation of study failures by a whistle blower led to major changes in U.S. law and regulation on the protection of participants in clinical studies. All the good thinking men and women of the world got together and charted out certain guidelines where use of humans for experimentation was concerned. Thus evolved medical ethics.

## Informed Consent in medical practice

Consent is an ethical principle. Medical treatment can only be performed with consent of competent patient. Giving the treatment without consent is failure to respect patient's autonomy, violating an individual's right to self determination. Any medical treatment given without consent is an action for trespass where damages are payable. Legally consent is when two or more persons agree upon the same thing in the same sense, they are said to consent as per the definition of consent given in section 13 of Indian Contract Act, 1872. Medical professionals are reminded that consent is taken under section 13 of the Indian Contract Act,

1872. This Act, however also provides under section 11 that only those persons above 18 years of age are competent to enter into a contract. Since doctor – patient relationship amounts to entering into a contract, it is advisable that consent should be obtained, specially written consent, from parents / guardian of a patient who is below 18 years so that validity of the contract is not challengeable. Under section 53 (2) of the code of Criminal conduct, whenever a female is to be examined, it shall be made only by, or under the supervision of a female doctor. Section 10 of Indian Contract Act, the consent should be free consent.

Consent in the context of the practice of medicine concerns the following three situations. The first one is examination of the living patient for the purpose of diagnosis and subsequent treatment. The second situation is examination of living person for medico legal purpose and the third is post-mortem examination and removal of tissue for transplantation.

When a person comes to a doctor for an ailment it implies that s/he is agreeable to medical examination in the general sense. This constitutes implied consent. This, however, does not imply consent to procedures more complex than inspection, palpation, percussion and auscultation and routine sonography.

Anything other than implied consent is expressed consent. This may be either oral or written. Express oral consent is obtained for relatively minor examinations or therapeutic procedures, preferably in the presence of a disinterested third party. Express written consent is to be obtained for all major diagnostic procedures, general anesthesia, for surgical operations, intimate examinations, examination for determining age, potency and virginity, and in medico-legal cases.

With the medical science progressing in leaps and bounds and the current age being the computer age, the patients are well aware of their rights. They have access to much information and are usually full of questions whenever a doctor intends any intervention. Failure to satisfy the patient before start of intervention has been the basis of innumerable litigations and this has brought in the concept of "Informed Consent". Information is given to the patients in print. Adequate information is given about the necessity, nature and limitation, consequences and the risk of the intervention. Alternative modes of treatment if any are also

## Editorial

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offered to the patient Such informed consent must be obtained in the presence of a witness who should affix his or her signature to state so, prior to every intervention. Informed consent is free and voluntary. Consent given in medical profession should be with free will and accord and not by fraud, mistake or misrepresentation.

Situations where consent may not be obtained are medical emergencies needing to save life or future health, immigrants, members of armed forces, a person suffering from a notifiable disease, handlers of food and dairy milk, new admission to prison, court order for a psychiatric examination or treatment, persons brought for medical examination by police like a case of alcoholic intoxication, sexual assault. No consent of the patient is required for the medical examination but no treatment can be enforced without consent of the patient .In case of arrested person

brought by police to take blood sample or sample of hair or anything required for evidence, even reasonable force can be applied to obtain sample.

The researcher/doctor may have the best interest of the patient at heart. But if the patient /person refuses the treatment/intervention then it is the doctor's duty to respect the person's choice. It is obvious that consent form is an important document which should be properly filled, signed and preserved in medical records. Any blanket consent becomes an invalid consent and should be avoided in medical practice. The consent form is for the patients to acknowledge that the nature and purpose of treatment has been fully explained, understood and consented to. Doctor's should remember that patients never consent to doctor's negligence but only to risks and complications of the intervention.