Review article:
Informed consent in clinical practice and research: ethical and legal perspective
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Abstract:
Informed consent is a critical document in clinical trials and healthcare service. In past few decades, Informed consent and good clinical practice (GCP) has gained considerable attention globally, due to continuous litigations between the patients and the doctors and rise in number of research studies and randomized controlled trials (RCT) specifically in developing countries. Several studies have revealed lack of awareness for consent process in general population and medical professionals as well. It is the ethical and legal duty of the doctor to inform the patient about the procedure and associated information, but this document is equally important to the medical practitioners to prevent any false prosecution against them in the court of law. Several recommendations have been put forth by the committees and legal courts in regards to this matter, however, a universal guideline for the informed consent process and assuring safety of patients and participants in clinical trials is missing.

Keywords: Clinical trials – Consumer protection act - Good clinical practice – Ethics - Informed consent

Introduction:
Instead of 'buyer beware', it ought to be 'buyer be aware'. No need to attach an element of fear to keeping ourselves informed! – Brandon A. Trean

With a growing awareness and knowledge of human rights and medical ethics, the consent has become an integral document for any medical and healthcare organization. The doctrine of consent is not new but can be traced back to ancient times which proceed with constant controversies and evolution1-3

There is no strict legal definition of the consent but Sec. 13 of the Indian Contract Act (Indian Contract Act, 1872) states that "two or more persons are said to consent when they agree upon the same thing in the same sense". This has been reflected clearly in Article 21 of the Indian Constitution, which states that "No person shall be deprived of his life or personal liberty except according to the procedure established by law" 4

Various literatures and agencies define consent in their own terms such as:-
“voluntary consent given by a person or a responsible proxy (e.g., parent) for participation in a study, immunization program, treatment regimen, invasive procedure, etc., after being informed of the purpose, methods, procedures, benefits and risks.” 5
and “voluntary authorization, by a patient or research subject, with full comprehension of the risks involved, for diagnostic or investigative procedures, and for medical and surgical treatment”6

www.ijhbr.com ISSN: 2319-7072
All these definitions underline the importance of trust and the act of doctor in favour of patient wellbeing in a well informed and documented manner. There are common misconceptions associated with the informed consent (IC) process. One study reveals that almost 46% of patients in the study were under the impression that the major goal of an IC is to protect the hospital from litigation. In addition, 68% of the patients were convinced that the IC process gives the doctor control of what is going to happen and with rise in awareness and knowledge among general population; the need for such document has become more imminent in the present era for the doctors as well for patients. This article with extensive search of national and international literature and author’s understanding is an attempt to explain the role and medicolegal aspects of the informed consent in simple yet comprehensive manner in form of the answers to the frequently asked questions on the topic.

**What is informed consent?**

An informed consent in broad terms is an agreement by and between the patient or its legal guardian and the consulting doctor confirming that the patient or the guardian has been informed and understood about the disease or the condition, procedure planned, associated risk and complications, prognosis, alternative treatment available and other relevant information by the doctor and the patient agree upon them voluntarily, unbiased and under physical and mental state enabling him to give the consent.

The above description of an ideal consent clearly indicates three key requisite for this document to be valid. First, a consent should be voluntary, unbiased and given by the patient in free will. Secondly, it should be informed i.e. the patient or the subject prior to consent should be well informed in detail about the procedure, associated benefits, risk and complications and alternative treatment options available. Last but not least the patient should be in capacity, physically and mentally to give the consent for the treatment or the procedure.

Hence, consent can be considered as an agreement of mutual understanding for the services by the doctor and the patient as the consumer under Consumer Protection Act.

**Who can give the consent?**

Any individual who is “major” as per law can give consent for himself, provided his physical or mental condition allows him to enter into such agreement. In case the subject is minor or cannot give consent as discussed earlier, the consent on his behalf can be given by the legal guardian who fulfils the prerequisites for the consent and is legally responsible for subject’s care, health and wellbeing. Parents, sons or daughters, siblings or spouse are the most commonly and acceptable legal guardians. In few countries, informed assent can be received by the child for the treatment but there are no clear standards defining the legal and ethical acceptability of the consent or assent in paediatric age group.

The physical and mental conditions which restricts the subject from giving consent may include physical handicap causing inability to sign or put thumb impression, altered consciousness, vision loss, diminished IQ (mostly seen in geriatric population), under influence of drugs (alcohol, narcotics, sedatives, hormones, etc.), under severe stress or mental disorders, etc.

It is noteworthy that the above mentioned conditions are not a strict criteria to refuse the subject to sign the inform consent but as a thumb rule, the subject cannot give a valid informed consent where, as per expert opinion, he has any condition which limits the subject capability of understanding, prevents him from communicating
his consent or his decision making capabilities including his acceptance for the need for medical intervention at the time of consent process. Except for the above mentioned situations or other cases where consent from the patient is not eligible or feasible, the consent should always be obtained by patient himself.

**What should be there in consent?**

One of the most important and the widely neglected aspect of informed consent is its matter or the content. In clinical trials, the informed consent can be approved by institutional review board (IRB). However, in medical centres, hospitals and healthcare units the consent is usually found as a pre-typed document as per the understanding of the doctor and the legal advisor which is although convenient but not advisable. It is important that an informed consent should contain the following points:

1. Disease or condition of the patient
2. Treatment/procedure planned or advised
3. Benefits of the treatment and prognosis
4. Associated risk and complications
5. Alternative treatment options available (including option of no treatment)
6. Any past or existing medical condition/history which may affect the outcome or course of the treatment
7. Miscellaneous (which may include the approximate duration of the stay, cost, affiliation, funding or sponsorship for the clinician or the institute and other relevant factors and conflicts of interest)

All the above information should be clearly mentioned in the consent in simple and clearly understandable by the patient, guardians, consulting doctors and the authorities. Studies suggest that the content and the language in consent form are often difficult to understand.

The consent should carry signature of the patient or legal guardian, name and address, date and place of consent and signature by minimum one witness whenever possible, who is not associated with the consulting doctor or institute in any way.

In case the consent is given by the legal guardians, caretaker or the authority the note should be made regarding the condition of the patient restricting him from giving consent along with the relationship and legal right to give consent on patient behalf.

Consent for life threatening situations (but not an emergency) or high risk surgeries should be more elaborative and more documentation of the notes are expected from the consulting doctor and nursing staff.

Proxy/surrogate consent where patient is incapable of giving consent himself, proxy consent by physician himself under life threatening emergency or absence of decision maker are applicable in some circumstances such as critically ill patient and geriatric age group with advanced disease.

**What is role of the medical staff and the patient in consent process?**

The doctor is responsible for providing all the necessary details regarding the procedure which is in the best interest of the patient health and wellbeing in patient vernacular language without forcing the patient or the guardian for the decision. The doctor should also provide an option for second opinion or referral to other healthcare centre in case the situation permits. The nursing staff can play important role in helping the patient to take an unbiased and well informed decision.

The doctor is also entrusted to maintain patient confidentiality, assess and quantify the condition of the patient and evaluate the validity of the consent and legal guardianship under circumstances. The patient and the relatives role includes understanding all the aspects of the treatment and
the consent form to take a judicious and autonomous decision which is in best interest of his health and respect patient-doctor relation.

When consent is not needed?
Whenever possible, an informed consent should be obtained from the subject, however, there are situations where the consent is not necessary. If the subject condition is life threatening and the proxy is not available then the doctor or the hospital can treat the patient without his consent. Hospital can induce certain treatment to mentally impaired patients where consent is not feasible. As per Section 53 (1) of Code of Criminal Procedure, law enforcement agencies or judiciary can order certain medical examination against person’s will and consent. Other cases may include government orders for examination, testing, specimen collection, and treatment in cases of pandemic, untreatable diseases.

Consent in Clinical research
As per the article 7 of the Covenant on Civil and Political Rights which states that ‘No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation’. The aim of informed consent document in clinical trial is to inform the subject of the risks, rights, and benefits of participation in a study. Informed consent, while not always necessary, is a critical document for research involving human subjects. As per Indian council of medical research (ICMR) guidelines, every participant should be provided with ICD and patient information sheet with necessary details regarding the study. Special considerations and attention should be made in the research involving human embryos, genomic studies and pregnant females. Consent is also mandatory for participation in clinical research and use of personal, medical details and photographic records revealing identity of the patient for the purpose of publication. Multimedia and audio-visual aids have been effectively used as a means of better understanding of the research process, a neutral educator or medical assistant can be helpful in communicating and in depth discussions with research participants and clarify their doubts.

Legal implications
There is no blanket consent or standard format for the consent. Consent is limited to specific patient, doctor and the procedure and a single consent cannot cover other patients, change in consultant or deviation from the procedure and is otherwise considered as “battery” and can be hold against the doctor or institute in the court of law. Proper time and information should be given to the patient before the decision until and unless there is case of emergency. According to the findings of the apex court in a case, consent from the relative is not valid merely because the patient is under anaesthesia and the surgeon wishes to alter or perform additional procedure except in emergency situations where no other option exist. The medical profession carries therapeutic privilege. In case the doctor feels that any specific information may harm the patient health or the recovery process then the doctor can hold the information from the patient but it should be shared by the care takers and guardians with proper counselling and should be carried out under rare and reasonable circumstances only.

Further the experience/competence of the surgeon and facilities of the hospital can be brought into question in an event of complication until and hence the right for second opinion or referral to specialist or higher centre should always be provided to the patient in elective procedures. How much information to be disclosed to the patient is another important question. In the eyes of
the law, “adequate information” should be disclosed (as discussed in this article somewhere before) which enables the patient to take an informed and balanced decision and at the same time not compelling the patient mind to enter into particular treatment\[^39\].

In case the patient refuse to undergo any procedure or treatment despite of doctors advise, then in such case the doctor should respect the decision and “informed refusal” should be documented informing the consequences to the patient. But this liberty should not extend on the rights of others or cause harm to a third party or community. Similarly, discharge against medical advice should be properly recorded in the case sheet with signature of the patient and/or the guardian\[^34\].

There are lot of issues regarding informed consent in randomised controlled trials and placebo as how one can disclose the information of uncertainty of the treatment for the patient (whether the patient will receive the gold standard treatment or the placebo as control or the trial therapy?) without conflicting the basic principles of such trials\[^40, 41\].

“One cannot know with certainty whether a consent is valid until a lawsuit has been filed and resolved.”

As quoted by the supreme court of California, the above statement reflects the necessity and ambiguity for the informed consent\[^34, 42\] while the consent remains the leading cause of dispute between the patient and the doctor\[^37, 39\]. However, fortunately the honourable Supreme Court of India has recommended the guidelines for cases of alleged negligence against medical practitioners in India in order to safeguard the doctors against false prosecutions and preventing doctor’s arrest in such cases\[^43\].

**Conclusion**

Informed consent is an integral part of treatment process and clinical trial. It is important and the moral right and responsibility to make the patient aware about the pros and cons of the any medical procedure or intervention. Despite of long history and active efforts by various committees and agencies there is general dilemma among general practitioners and scientists in regard to informed consent. Association of medicolegal expert by the hospitals can reduce this grey area in day to day practice. Universal guidelines and standard protocols are needed along with continuing education to ensure patient safety and built a strong patient-doctor relationship.

**Declaration**

This article does not provide any explanations for the guidelines by the governing agencies; rather express the views of author based on their understanding and review of literature. As expressed earlier, the final decision lies with law based upon the act of patient and doctor in their best interest.

**References:**


Table I- Key points to be incorporated in patient information sheet as per ICMR guidelines.

<table>
<thead>
<tr>
<th>Key points</th>
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<tbody>
<tr>
<td>Nature and purpose of the study clearly stating it as a research</td>
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<tr>
<td>Expected duration of participation in the study with number of participants</td>
</tr>
<tr>
<td>Procedures to be followed</td>
</tr>
<tr>
<td>Investigations, if any, to be performed</td>
</tr>
<tr>
<td>Foreseeable or expected risks and discomforts adequately described and whether project involves more than minimal risk</td>
</tr>
<tr>
<td>Benefits to participants, community or medical profession as may be applicable</td>
</tr>
<tr>
<td>Steps taken for ensuring confidentiality</td>
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<tr>
<td>Statement for no loss of benefits on withdrawal</td>
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<tr>
<td>Benefit sharing in the event of commercialization of the project</td>
</tr>
<tr>
<td>Contact details of principle investigator (PI) or local PI/Co-PI in multicentric studies for asking more information related to the research or in case of injury or serious adverse event (SAE)</td>
</tr>
<tr>
<td>Voluntary participation of the subject</td>
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<td>If the study involves test for genetics and HIV, counselling for consent for the testing must be given as per national guidelines</td>
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<tr>
<td>Storage period of biological sample collected in the study and related data with choice offered to participant regarding future use of sample, refusal for storage and receipt of its results</td>
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