Informed Consent in Clinical Trials: Role of Institutional Ethics Committees and NGO Interventions

P.C. Harigovind

I. INTRODUCTION

MEDICAL experimentations are something that takes place in every doctor's office (1). These researches always involve high risk and responsibilities (2). The law prescribes that the voluntary consent of the trial subject is always essential for the experimentations over human subjects (3). The law ever made after the Nuremberg trial always demands for the full consent from the trial subjects for conducting human experimentations. Nuremberg code mentions it as voluntary consent and at present the rule had developed into informed consent. It is the duty of physicians to narrate things to the trial subjects in detail. Every consequences of being a party to the trial should be made known to the patient and with such knowledge in mind the subject has to make his consent. Thus the informed consent derived from a patient or trial subject has many fold implications over the entire process of human experimentation. Informed consent can thus be called as the elementary and imperative clause that regulates the entire process of human experimentation.

II. JURISPRUDENCE OF INFORMED CONSENT

The term informed consent was not used by the Nuremberg code and was first appeared in the Helsinki Declaration, 1964 (4). The declaration also give the power to a trial subject to withdraw the consent at any movement of trial and to abstain himself from any further experimentations. To know the relevance and meaning of informed consent it equally important to understand the role played by the doctrine in physician-patient relationship. Patient's right to know about the disease, treatment and its impact over life is well related to his quality of life (5). In health care system, the concept of quality of life is an age old doctrine and well approved even in the time of ancient Greeks (6). In every case the need of any patient is to have some affirmative action in preserving his life. This aspiration of a patient entitles him with the right to know about the kind of treatment administered over him. This aspiration is justified with the help of hedonistic theory (7). The concept of good life and the affects made by it to the quality of life is well addressed by hedonistic theory. The hedonistic calculus demands the health care system to offer maximum assurance to quality of life so as to increase its utility.

The patient's right to decide the outcome of his treatment is also a concern of informed consent. This proposition can be understood in situations of terminally illness. If no fruitful treatment is available, it's the right of the patient to decide for prolonged medication and treatment. This decision making power cannot always recognized as a unique standard for health care system. The power to exercise the right depends upon the disease he faces with. For example in case of a cardiac arrest or a severe injury by motor accidents etc the patient may not be in a position to make his decision over the right. But in most other cases, especially where options are live before a patient he can make his choice. So comes in the case of human experimentation also. The decision making power plays a vital role here as the physician prescribes a new method of cure where a known science is available. The decision so made by the patient on the explanations given by a physician still casts some dilemma. The way in which the physician explanations get into the mind of a trial subject is perplexing (8).

Apart from the above reasoning, the need for consent is also evident from the doctrine of body autonomy. Body is also recognized by law as a property and any interference with the body material against one's consent will be nothing but trespass and hence constitutes a criminal offence. It can always risk subject's health and life and is thus a matter of greater human concern (9). Autonomy is one of the fundamental values that should regulate any kind of experimentations over human subjects. Informed consent can be called a rule which is completely relied on autonomy. Autonomy is an extremely slippery concept. Perhaps at the core of the concept of autonomy is the idea that people should

P.C. Harigovind, Research Scholar, School of Legal Studies, Cochin University of Science and Technology, Cochin-22, Kerala. E-mail: harigovindpc@gmail.com
be able to rule themselves rather than be ruled by others. The Kantian conception of man as an end in himself will bind with the concept of autonomy.

Law discusses about two different concept of autonomy. One is the libertarian concept and another one is the liberal concept of autonomy. In the libertarian conception the state or any private interest will violate the right to autonomy while interfering with the decision making power of a person unless and until the decision generally makes any public wrong. This kind of approach does not have any paternalistic concern for the subject's right. On the other hand the liberal concept is wedded with this paternalistic concern. Informed consent is addressed as liberal concept of autonomy. The law demands the consent to be informed as it have a paternal care towards its subjects. On the other hand the libertarianism stands for the actual consent of the subject irrespective of the fact that how far it is informed. Thus the concept of autonomy is also there behind the construction of the doctrine of informed consent. Anyhow the entire process of human experimentation starts with the availability of volunteers for trials and this initiate with availing consent from the trial subjects.

- **Informed Consent: The legal Formalities**

From Nuremberg Code and Helsinki Declaration, informed consent runs as one of the prominent rule for human bioethics. The need for consent is also declared mandatory by the recent U.N. Documents (10). It demands for providing all adequate information with respect to the kind of treatment or experimentation done over a person (11). Apart from this it is also mandated that such trial subjects will be entitled with the right to withdraw their consent (12). The declaration also emphasis on the inter relation between the human dignity, medical ethics and informed consent. It is internationally recognized that the waiver of informed consent cannot be made ordinarily but in all exceptional cases the investigator have to get the approval from ethical review committee (13). This guideline in its commentary part also attempts to draw an international definition for the term informed consent. It is made that (14):

Informed consent is a decision to participate in research, taken by a competent individual who has received the necessary information; who has adequately understood the information; and who, after considering the information, has arrived at a decision without having been subjected to coercion, undue influence or inducement, or intimidation.

Thus the concept of contracting can be read into the makeup of every informed consent. The consent made by the subject free from any kind of influences and one should not be inducted into the trial by bad consent. The freedom of choice based on individual autonomy is the principle behind the entire concept of informed consent. Two or more persons are said to consent when they agree upon the same thing in the same sense (15). While making a contract, the consent should not be caused by coercion, undue influence, fraud, misrepresentation or mistake (16). So made consent will be treated as informed when it is an act of reason accompanied by deliberation of mind which can know the right and wrong, good and evil. Thus informed consent will represent the active will of the person who makes the consent.

In the case of medical law, consent will operate more as an ethical doctrine than as legal norm. Informed consent attains such a shape by virtue of the fact that it has much impact over the individual dignity and their self determination capacity. Seeking consent tries to create the optimal relationship between doctor and patient, namely a partnership of shared endeavor in pursuit of the client's interests (17). The entire procedure of consenting in medical law involves high reverence towards personal autonomy. From this perception it is evident that a doctor cannot even touch his patient without his consent. Treatment without consent can even become an offence of battery. The doctrine of informed consent signifies consent of patient obtained after true and full disclosure of information regarding diagnosis, alternative methods of treatment with their relative risks and benefits and known material risks of procedure (18). As the doctrine encompasses all the knowhow's of disease and possible ways of cure, it makes one of the most relevant procedures in case of drug trials and any form of human experimentation. In any case of treatment, if the consent from a patient is extracted without the proper disclosure of material facts of treatment, the consent so obtained will be regarded as legally invalid. Defective or inadequate information of treatment will disable the patient to make his rational judgment in submitting oneself to treatment.

The old doctrine from *Hippocratic corpus*, every physician has to conceal many things from the patient which appears to be prejudicial to the patient's health or wellbeing (19). The era when doctor acted as parent of the patient was gone and the new concept of fiduciary relationship came into being. No exclusive right to treat a patient is there in the present system of medical treatment for a physician. New system of medical treatment evolved along with the doctrine of informed consent. On one side it is argued that the main reason behind the evolution of informed consent is the high consciousness over personal health and fitness. It is equally argued that the concept had evolved from the Nuremberg experiences. In fact the doctrine got wide acceptance only by last few decades (20). The patients now are more cautious about the treatment administered to them and this cautiousness was created by the new perception of the human right doctrine of bodily autonomy.

Even the doctrine of informed consent has been widely accepted and followed by almost all medical professionals it has not yet attained a specified shape. To what extent a doctor have to disclose about the treatment still remains vague.
Two different standards have been evolved to deal with this issue and they are (1) the prudent patient test, (2) the reasonable doctor test. In the prudent patient test, the doctor has to disclose all those details which a cautious patient considers to be material from patient's standpoint. In reasonable doctor test the physician community tries to raise a unique standard from their side. Here the doctors have to disclose all the details which another doctor will do in same instance. It is true that the doctrine succeeded in introducing better consensus between doctor and patient in medical treatment. The doctrine was originated in an American case law (21). In this case the claimant was subjected to a surgery in which there was an inherent danger of paralysis. The same was not informed by the surgeon and the patient was inflicted by paralysis. The court held the surgeon to be liable and there by developed the standard of informed consent. It was only few years prior to this judgment, the Nuremberg Code was adopted where the concept of consent was discussed in detail in need of medical interventions. But the Code does not demand such consent to be informed. The American case law marched forward holding that (22):

A physician violates his duty to his patient and subjects himself to liability if he withholds any facts which are necessary to form the basis of an intelligent consent by the patient to the proposed treatment.

In America the law clearly advocates for informed consent and the only dispute is on the mode of its application; either to go with prudent patient norm or with the reasonable doctor version.

In England the doctrine of informed consent was adopted through a high court judgment (23). By this judgment the court required the medical professional to make it clear to the patient about the treatment and the risks involved in the treatment as every doctor do in similar circumstances. Another decision from England is of very importance as it involves multiple explanations for the doctrine of informed consent (24).

Informed consent itself is not well designed and judiciary had varied on its opinion to the extent of disclosure of facts relating to patients health by a physician. Sidaway's case (25) talks much on that. Different standards were set by judges in the above case. Lord Scarman developed the test of prudent patient on the basis of a reasonable patient standard. By prudent patient test, the physician has an extensive duty of disclosure towards the patients. The only ground on which the physician can withhold the information is on the therapeutic privilege. Therapeutic privilege allows the physician to withhold the details with regard to the treatment if it appears to be unfavorable to patients physical or mental well being. In contrast to the above opinion, Lord Diplock suggested the standard of a reasonably competent practitioner who always keeps his skill and judgment to improve the patient's health. The question of negligence towards informed consent will arise only if the non disclosure of any matter generally appears to medical community with relevant expertise as inappropriate. To the same matter, Lord Templeman responded differently way with all others. According to him the final decision is always with the patient and patient can have more information interacting with the physician. No patient can expect too much information as it will become an impediment to balanced judgment in medical treatment. The above variations in the judicial opinion itself indicate the complex nature of the doctrine of informed consent. Informed consent thus will fail to serve its actual intentions and objectives in clinical drug trials. The need for rethinking the doctrine of informed consent in clinical trials is envisaged as fundamental (26). Research on this context effectively noticed the incapacity of the doctrine to serve as a universal norm. Any lapse in grasping information will also vitiate the accountability of informed consent. Hence it seems always fall short of public aspirations (27).

The Indian position on informed consent also evolved through many decisions. Statute only maintains that the consent for treatment to be attained in circumstances were it is demanded and should be obtained in writing (28). The Indian law regulating consumer grievances consider medical profession under its head. The patient consciousness about their rights had improved much in Indian society. In reality the law relating to informed consent is less understood and accepted in India and hence it is still in its infancy state. Only in few case laws the court reflected the idea of informed consent and thereby tried to design its legal premise. But as the time goes on, the doctrine of informed consent and its relevance in medical treatment is being realized by the judiciary and the society at large.

Even in instances where the doctor failed to make the right treatment and thereby caused serious injuries to the patient the judiciary does not looked upon the relevance of taking informed consent from the patient (29). In another case law the court held that the concept and conditions for consent that made in Indian Contract Act, 1872 is to be complied in medical treatment too (30). It was made the obligation of every doctor to ensure that he had taken consent from the patient by free and fair means (31). Even though the concept of informed consent is not well established by this judgment, it clearly focused the importance of consent in medical treatment. The exact picture of consent in medical treatment is made out by Supreme Court in Samira Kohli (32) judgment. The judgment mandates the physician to obtain real and valid consent from the patient before commencing the treatment. In the course of obtaining such consent the physician have to impart adequate knowledge that will help a patient to make a balanced decision. The doctor has to make the patient know about the nature and risk of the treatment and also about the alternatives available. Consent for diagnosis and therapeutic remedy are to be taken differently.
• **Consent to Human Experiments**

Human experimentations were regulated with the doctrine of consent even before the Nuremberg Trials (33). The Neisser Case (34) was of such kind where Albert Neisser, a dermatology professor made serum trials for patients with syphilis against their will or knowledge. The court to this issue demanded the need for consent from the patients despite the medical authority of Neisser in therapeutic care and was fined. In an advice to the ministry, the lawyers stated such trials to constitute criminal liability if done against the will of the patient in non therapeutic trials (35). In 1931 as a part of its criminal law reform, the German government made new guidelines for new therapy and human experimentation which set out certain serious precautions (36). According this guidelines new therapy can be introduced even without the consent of the patient in emergency situations. On the other hand non therapeutic research was only permitted after obtaining proper consent from the patient. It is remarked that this documents prior to the Nuremberg Code do have even discussed about the possibility of constituting institutional review boards but failed in the attempt (37). Thus it is evident that the doctrine of informed consent had its implications to some extent even before the Nuremberg Code (38).

To obtain the patient's consent for clinical trials is mandatory but not an easy procedure. In formulating the informed consent from a patient the crucial question arise is about the extent of information that to be made to the patient about the trial. Explaining the impact of a new therapy even in the case of therapeutic trial is not that easy and is more complicated in non therapeutic trials (39). As observed earlier in this article the expectation and grasping capacity of the patient will vary and the same cannot ever be an excuse to any adverse incident in the course of the trial (40). In obtaining consent for experimentations always consent forms should be used which will help the researchers for future references before the ethical boards and the copy of the same is to be provided to the patient concerned. The presence of a witness will add more credibility to the consent so obtained (41).

The very presence of word "informed" means to be someone who is instructed properly and knows the facts about the trial. In the case of clinical trial the word informed will not always have the same impact as used in the case of treatment. Normally in the case of randomized trials most of the information will not be adequately provided. It is also equally relevant to note that the law also does not emphasis the need of conveying all adequate information (42). There exist some substantial differences between the processes of seeking informed consent and obtaining the same. Seeking the informed consent is only an ethical obligation but on the other side obtaining it depends upon the researcher involved in the process. The process of obtaining informed consent in most of the cases is taken as a bureaucratic form filling process and should not be like that (43). The researcher have to put a design to the questions and explanations that to be communicated to the trial subject. Communication and its precision make the entire basis for the nicety to the objective of informed consent. The legal principle of adequate information or reasonable information in the case of therapeutic care cannot be the one for experimentations. The researcher has to communicate whole information and make the trial subject convinced about the misfortunes in every trial.

Legally, we look whether the consent given by the parties to a trial are free and informed. As we mentioned earlier this cannot be far and final criteria for adducing fairness for trial process. The so obtained informed consent should also be clear about the understanding of the trial subject about the project he is consenting to. **Hans Jonas** identifies this as the quality of the authentic consent (44). More to the concept of authentic concept, the workability of the doctrine is also dependent on the factors like the mind set of investigator, the primacy given to the autonomy of the trial subject and the method adopted for the conversation (45). The rule of informed consent, demands the following disclosures to become a true consent (46):

1. that the subjects are not only patients and to the extent, which they are patients, that their therapeutic interests, even if not incidental, will be subordinated to scientific interests; (2) that it is problematic and indeterminate whether their welfare will be better served by placing their medical fate in the hands of physician rather than investigator; (3) that in opting for the care of a physician they may be better or worse off and for such and such reasons; (4) that clinical research will allow doctors to penetrate the mysteries of medicine's uncertainties about which treatments are best, dangerous or ineffective; (5) that clinical research may possibly be in the patients immediate best interest, perhaps promise benefits in the future, or provide no benefit, particularly if the patient is assigned to a control (placebo) arm of study; (6) that research is governed by a research protocol and a research question and, therefore, his or her interests and needs will yield to the claims of science; (7) that physician-investigators will respect whatever decision the subject ultimately makes.

The above observation made herein also have many drawbacks from the human rights standpoint. The conception that the therapeutic interest of the patient will be subordinated with scientific interest is presented with much vagueness. The impact of the same will vary depending on the stages in clinical trials. In phase I trial the subject will not be having any therapeutic interest but only scientific or monetary interest. In the forthcoming stages the extent of therapeutic interest is relative. There the trials subjects have to look for the alternative therapeutic cures for their disease or get properly convinced about the risk involved in the trial and the above contention by Jay Katz is concerned only about the latter. Analyzing the fourth point, it seems that it will never becomes a concern for any research subject in spite of his
status being a patient or non patient to reveal the safety and efficacy of any drug. All these points emphasize the incapability of the doctrine of informed consent to ensure human rights of trial subjects.

III. CONCLUSION

The doctrine of informed consent emerged as milestone in the history of medical profession. Historically doctors were given eventual trust by the patient community for their concern for the well being of patient community (47). The bitter experiences of research activities conducted by the Nazi doctors lead to the invention of this doctrine. This doctrine may be sound enough to assure safety of the patients in the case of treatment. Above all this can be called as an American doctrine suited for a developed society. India is not yet fit to accommodate such a doctrine in need of safety of her illiterate patient community. Looking back, the doctrine will appear as a contribution of judiciary (48) and it is not yet having a specific form or definition. Many privileges which can be attracted by a physician in case of treatment cannot be extended to the case of experiments over human beings (49). In short, the doctrine in its present form cannot tackle the vulnerable position of trial subjects. Even the presence of strong REC's cannot make the situation better. A codified piece of norms on informed consent and its rigid compliance is highly required.

REFERENCE

[2] Ibid.
[6] Id, P.475.
[7] Ibid.
[12] Id., Art. 6 (2).
[14] Ibid.
[16] Pollock & Mulla, Indian Contract and Specific Relief Acts (12th edn. 2001), Butterworth's, New Delhi, p.398.
[22] Id, p. 575.
[27] Id., p. 154.
[31] Id. p.195.

[34] Ibid.

[35] Id, p. 1446.

[36] Ibid.

[37] Ibid.s

[38] Supra, n. 33, p. 1447.


[40] Id, p. 735.

[41] Supra, n. 39 p. 736.


[46] Id p. 34.


[48] The doctrine has its birth in Nuremberg Trial made over Nazi Doctors. The Nuremberg Code which emphasizes over the need for consent is a contribution of Nuremberg Trial.