



# Informed Consent in Clinical Trials and the Role of Institutional Ethics Committees: A Socio-Legal Analysis

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## Abstract

Experimenting new drugs on human beings, is one of the crucial human right issues faced by the third world countries in the present century. It is true that the international law had taken high concern of this social issue after the *Nuremberg Trials*. The international law mandates informed consent to be obtained from the participants of clinical trials and this is the sole mechanism through which the rights of the trial subjects are being protected. The public health issues caused by illegal and unethical trials over patients are now evident in Indian health care system. The issue has come up for consideration before the Supreme Court of India recently. In India the law runs in tune with the international parameters for conducting human experimentation. The law on informed consent has a fatal impact over public health care issues, especially over the matter of clinical trials. Recent experiences in India reveal the threats caused to the society by clinical experimentations. Clinical trials and allied health issues are also brought to the notice of the judiciary. The law on informed consent in India is in its infant state. Exploring the doctrine of informed consent is crucial to this study. The present issue of clinical research which threatens the health care

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system is analysed and the doctrine of informed consent to regulate the system is assessed to check its efficacy and veracity. Analysis of the issue will help to communicate to the public about the need for better exercise of the rights of those who are subjected to clinical researches. The law of informed consent is in many ways inadequate to deal with the issues relating to clinical trials in India. The doctrine of informed consent has to be redefined to a great extent. The institutional review boards and Non-Government Organisations (NGO) can play a vital role in assuring proper observation of rules relating to regulation of human trials.

**Keywords:** Clinical Trials, Consent, Ethics, Experimentation, Health.

## Introduction

Medical experimentations are something that takes place in every doctor's office.<sup>1</sup> These researches always involve high risk and responsibilities.<sup>2</sup> The law prescribes that the voluntary consent of the trial subject is always essential for the experimentations.<sup>3</sup> The laws made after the Nuremberg trial demands for the procurement of full consent from the trial subjects for conducting human experimentations. The Nuremberg code mentions it as voluntary consent and at present the rule has developed into informed consent. It is the duty of the physicians to appraise the trial subjects about the experimentations in detail. The 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 provide his consent. Thus the informed consent derived from a patient or trial subject has manifold 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.

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<sup>1</sup> Michael B. Shimkin, *The Problem of Experimentation on Human Beings*, 117 SCIENCE NEW SERIES, 205 (1953).

<sup>2</sup> *Id.*

<sup>3</sup> See The Nuremberg Code, *Trials of War Criminals before the Nuremberg Military Tribunals*, 2 Control Council Law No. 10, 181 (1947).

## Jurisprudence of Informed Consent

The term informed consent was not used by the Nuremberg Code but first appeared in the Helsinki Declaration 1964.<sup>4</sup> The declaration also gave the power to a trial subject to withdraw the consent at any time during the trial and to abstain himself from any further experimentations. To know the relevance and meaning of informed consent it is 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.<sup>5</sup> In the health care system, the concept of quality of life is an age old doctrine and well approved since the time of Greeks.<sup>6</sup> 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 to him. This aspiration is justified with the help of the hedonistic theory.<sup>7</sup> The concept of good life and its effects on the quality of life is well addressed by hedonistic theory. The hedonistic calculus demands the health care system to offer maximum assurance to the 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 terminal illness. If no fruitful treatment is available, it is the right of the patient to decide for prolonged medication and treatment. This decision making power cannot always be recognized as a unique standard for the health care system. The power to exercise the right depends upon the gravity of the disease. For example in case of a cardiac arrest or a severe injury by motor accidents the patient may not be in a position to take an appropriate decision. However in most of the other cases, especially where options are available to a patient, he can make his

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<sup>4</sup>See World Medical Association, Helsinki Declaration, (1964) Principles 22 & 23, available at <http://www.wma.net/en/30publications/10policies/b3/17c.pdf>.

<sup>5</sup> Ivan Barofsky, *Patients' Rights, Quality of Life and Health Care System Performance*, 12 QUALITY OF LIFE RESEARCH 473, 481 (2003).

<sup>6</sup>*Id.* at 475.

<sup>7</sup>*Id.*

choice. 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 made by the patient on the explanations given by a physician still casts some dilemma. The way in which the physician's explanations get into the mind of a trial subject is perplexing.<sup>8</sup>

Apart from the above reasoning, the need for consent is also evident from the doctrine of body autonomy. Human body is also recognized by law as a property and any interference with the body material against one's consent would amount to trespass and hence constitutes a criminal offence. It can always risk subject's health and life and is thus a matter of great concern.<sup>9</sup> Autonomy is one of the fundamental values that should regulate any kind of experimentation over human subjects. The doctrine of informed consent completely relies on autonomy. Central to the concept of autonomy is the idea that people should be able to rule themselves rather than be ruled by others. The Kantian conception of man as an end in himself can be read 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 amounts to a 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 has a paternal care towards its subjects. On the other hand, the libertarianism stands for the actual consent of the subject irrespective of the fact how far it is informed. Thus the concept of autonomy has facilitated the construction of the doctrine of informed consent. The entire process of human experimentation

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<sup>8</sup> J. K. Wing, *The Ethics of Clinical Trials*, 1 J. MED. ETHICS 174 (1975).

<sup>9</sup> M. Cheriff Bassiouni et. al., *An Appraisal of Human Experimentation in International Law and Practice: The Need for International Regulation of Human Experimentation*, 72 J. CRIM. L. & CRIMINOLOGY 1597, 1603 (1981).

starts with the availability of volunteers for trials and this can be initiated by availing consent from the trial subjects.

### **Informed Consent: The Legal Formalities**

From the Nuremberg Code and the Helsinki Declaration, informed consent is accepted as one of the prominent rule for human bioethics. The need for consent is also declared mandatory by the recent U.N. Documents.<sup>10</sup> It demands for providing all adequate information with respect to the kind of treatment or experimentation done over a person.<sup>11</sup> Apart from this it is also mandated that such trial subjects will be entitled with the right to withdraw their consent.<sup>12</sup> The declaration also emphasises 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 has to get the approval from ethical review committee.<sup>13</sup> This guideline in its commentary also attempts to draw an international definition for the term informed consent. It states that, "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, inducement or intimidation".<sup>14</sup>

Thus the concept of contracting can be read into the makeup of every informed consent. The consent should be free from any kind of influences. 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

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<sup>10</sup> Universal Declaration on Bioethics and Human Rights, U.N.E.S.C.O., U.N. Doc. A/RES/2005/6 (Oct. 19, 2005).

<sup>11</sup> *Id.*

<sup>12</sup> *Id.*

<sup>13</sup> COUNCIL OF INTERNATIONAL ORGANIZATIONS FOR MEDICAL SCIENCES, INTERNATIONAL ETHICAL GUIDELINES FOR BIOMEDICAL RESEARCH INVOLVING HUMAN SUBJECTS 50 (2002).

<sup>14</sup> *Id.*

same thing in the same sense.<sup>15</sup> While making a contract, the consent should not be caused by coercion, undue influence, fraud, misrepresentation or mistake.<sup>16</sup> The consent thus made 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 a legal norm. Informed consent attains such a shape by virtue of the fact that it has tremendous 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 endeavour in pursuit of the client's interests.<sup>17</sup> 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. 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.<sup>18</sup> As the doctrine encompasses all the details of the disease and possible ways of cure, it makes one of the most relevant procedures in case of drug trials and any form of human experimentations. 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.

As per the old doctrine from the *Hippocratic Corpus*, every physician had to conceal many things from the patient which appeared to be

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<sup>15</sup> The Indian Contract Act, 1872, § 13.

<sup>16</sup> NILIMA BHADHHADE, POLLOCK & MULLA, THE INDIAN CONTRACT AND SPECIFIC RELIEF ACTS 398 (Butterworth 12<sup>th</sup> ed. 2001).

<sup>17</sup> IAN KENNEDY, TREAT ME RIGHT: ESSAYS IN MEDICAL LAW AND ETHICS 178 (Clarendon Press Oxford, 1991).

<sup>18</sup> Gerald Robertson, *Informed Consent to Medical Treatment*, 97 L.Q.R. 102 (1981).

prejudicial to the patient's health or wellbeing.<sup>19</sup> However new concept of trust and good faith underlies the doctor-patient relationship. On the 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 in the last few decades.<sup>20</sup> The patients now are more cautious about the treatment administered to them and this was created by the new perception of the human right doctrine of bodily autonomy.

Even though the doctrine of informed consent has been widely accepted and followed by almost all medical professionals it is yet to be formally structured. 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 the same instance. It is true that the doctrine succeeded in introducing better consensus between doctor and patient in medical treatment. The doctrine originated in an American case law.<sup>21</sup> 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 paralyzed. 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. Nevertheless, the Code does not

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<sup>19</sup> Harvey Teff, *Consent to Medical Procedures: Paternalism, Self-determination or Therapeutic Alliance?*, 101 L.Q.R. 432 (1985).

<sup>20</sup> EDWARD P. RICHARDS AND KATHERINE C. RATHBUN, *MEDICAL CARE LAW* 209 (Aspen Publishers 1999).

<sup>21</sup> *Salgo v. Leland Stanford Jr. University Board of Trustees*, 154 Cal. App. 2d. 560 (1957).

demand such consent to be informed. The 2<sup>nd</sup> district Court of Appeal of California held that:<sup>22</sup>

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.<sup>23</sup> By this judgment the court required the medical professionals to make it clear to the patient about the treatment and the risks involved in the treatment as every doctor would do in similar circumstances. Another decision from England is of importance as it involves multiple explanations for the doctrine of informed consent.<sup>24</sup>

Informed consent itself is not well designed and judiciary has had various opinions on the extent of disclosure of facts relating to patient's health by a physician. *Sidaway's* case<sup>25</sup> 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 therapeutic privilege. Therapeutic privilege allows the physician to withhold the details with regard to the treatment if it appears to be unfavourable to patient's physical or mental wellbeing. 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

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<sup>22</sup> *Id.* at 575.

<sup>23</sup> *Chatterton v. Gerson and Anr.*, 1 Q.B. 432 (1981).

<sup>24</sup> *Sidaway v. Bethlem Royal Hospital Governors and Ors.*, 1 All E. R. 643 (1985).

<sup>25</sup> *Id.*; See also JONATHAN MONTGOMERY, *HEALTH CARE LAW* 241 (Oxford University Press 1997).



nondisclosure of any matter generally appears to medical community with relevant expertise as inappropriate. Lord Templeman has given different opinion on the same matter. According to him, the final decision is always with the patient and the 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.<sup>26</sup> 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 always falls short of public aspiration.<sup>27</sup>

### **Informed Consent under Indian Law**

The Indian position on informed consent also evolved through many decisions. The law only maintains that the consent for treatment to be attained in circumstances where it is demanded and should be obtained in writing.<sup>28</sup> The consumer law in India governs aspects of medical negligence also. The patient consciousness of their rights has improved in India. 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

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<sup>26</sup> NEIL C. MANSON & ONORA O' NEILL, *RETHINKING INFORMED CONSENT IN BIOETHICS* 25 (Cambridge University Press, 2007).

<sup>27</sup> *Id.* at 154.

<sup>28</sup> The Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002.

judiciary did not examine the relevance of taking informed consent from the patient.<sup>29</sup> In another case law the court held that the conditions for consent as stipulated by the Indian Contract Act 1872 is to be complied with in medical treatment too.<sup>30</sup> It was made the obligation of every doctor to ensure that he had taken consent from the patient by free and fair means.<sup>31</sup> Even though the concept of informed consent is not well established by this judgment, it clearly focused on the importance of consent in medical treatment. The law relating to informed consent is clearly laid down by Supreme Court in *Samira Kohli*<sup>32</sup> 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 has to impart adequate knowledge that will help a patient to make a balanced decision. The doctor has to inform the patient 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.<sup>33</sup> The *Neisser Case*<sup>34</sup> was of such kind where Albert Neisser, a dermatology professor made serum trials for patients with syphilis against their will or knowledge. The court 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 would amount to criminal liability if done against the will of the patient in non therapeutic trials.<sup>35</sup> In 1931, as a part of its

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<sup>29</sup> Smt. Vinitha Ashok v. Laxshmi Hospital and Ors., 11 (1992) C.P.J. 372 (N.C.).

<sup>30</sup> Punjabi Nursing Home v. Kailash Marodia, 11 (2003) C.P.J. 194.

<sup>31</sup> *Id.* at 195.

<sup>32</sup> Samira Kohli v. Prabha Manchanda and Anr., A.I.R. 2008 S.C. 1385.

<sup>33</sup> Jochen Vollmann & Rolf Winau, *Informed Consent in Human Experimentation before the Nuremberg Code*, 313 BRITISH MEDICAL JOURNAL 1445 (1996).

<sup>34</sup> *Id.*

<sup>35</sup> *Id.* at 1446.

criminal law reform, the German government made new guidelines for new therapy and human experimentation which set out certain serious precautions.<sup>36</sup> According to these 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 these documents prior to the Nuremberg Code have even discussed the possibility of constituting institutional review boards but failed in the attempt.<sup>37</sup> Thus it is evident that the doctrine of informed consent had its implications to some extent even before the Nuremberg Code.<sup>38</sup>

Obtaining the patient's consent for clinical trials is mandatory but it is not an easy procedure. In formulating the informed consent from a patient, the crucial question arises about the extent of information that has to be made available 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.<sup>39</sup> 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.<sup>40</sup> 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.<sup>41</sup>

The very presence of the word 'informed' means 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 does not

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<sup>36</sup> *Id.*

<sup>37</sup> *Id.*

<sup>38</sup> *Id.* at 1447.

<sup>39</sup> Elizabeth Wager, Peter J.H. Tooley et. al., *Get Patients' Consent to Enter Trials*, 311 BRITISH MEDICAL JOURNAL 734 (1995).

<sup>40</sup> *Id.* at 735.

<sup>41</sup> *Id.* at 736.

emphasize on the need of conveying all adequate information.<sup>42</sup> 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 research 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.<sup>43</sup> The researcher has to put a design to the questions and explanations that has 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, the consent given by the parties to a trial are to be 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.<sup>44</sup> The workability of the doctrine of informed consent is also dependent on the factors like the mindset of the investigator, the primacy given to the autonomy of the trial subject and the method adopted for the conversation.<sup>45</sup> The rule of informed consent, demands the following disclosures to become a true consent:

(1) that the subjects are not only patients and to the extent, to which they are patients, that their therapeutic interests, even if not

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<sup>42</sup> M. J. Peckham, Carolyn Faulderet et. al., *Informed Consent: Ethical, Legal and Medical Implications for Doctors and Patients Who Participate in Randomized Clinical Trials*, 286 BRITISH MEDICAL JOURNAL 1117, 1118 (1983).

<sup>43</sup> Elizabeth Wager, Peter J.H. Tooley et. al., *Get Patients' Consent to Enter Clinical Trials*, 311 BRITISH MEDICAL JOURNAL 734, 737 (1995).

<sup>44</sup> Charles Fethe, *Beyond Voluntary Consent: Hans Jonas on the Moral Requirements of Human Experimentation*, 19 JOURNAL OF MEDICAL ETHICS 99, 101 (1993).

<sup>45</sup> Jay Katz, *Human Experimentation and Human Rights*, 38 ST. LOUIS U.L.J. 7, 28-34 (1993).

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 the investigator; (3) that in opting for the care of a physician they may be better or worse off (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 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; (6) that physician investigators will respect whatever decision the subject ultimately makes.<sup>46</sup>

The above observations 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. Analysing the fourth point, it seems that it will never become 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.

### **Informed Consent in Clinical Trials: Role of Ethical Review Committees**

The law requires the regular monitoring and review of clinical trials so as to ensure the safety and dignity of trial subjects. Informed consent from the subject by itself is not a complete doctrine to protect the human rights of the subjects. From the very beginning of a trial there should be an exact scheme for the trial and the same is modeled through a research protocol. The protocol

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<sup>46</sup> *Id.* at 34.

preparation and the review of the same by the ethics committee impartial and independent of the research institution is envisaged in the international documents. The role of ethics committee is well maintained in the Helsinki Declaration adopted by the World Medical Organization. This being a document made by the medical community, it could be biased. The working of ethics committees are not dependent upon these international documents but on the national legislations. In India, the constitution of ethics committees is maintained in the Drugs and Cosmetics Rules 1945. Schedule Y of the said rules in its appendix details the scheme for the constitution of ethics committees. It states that only the person who chairs the committee should be independent of the research institution. Apart from this only two or three members are independent of medical fraternity. The entire process of clinical trial always helps the members of medical community to earn more and they will always tend to promote trials and will be the bad guardian of subject's rights. The committee should consist at least of seven members and there should be some members who represent the community of social scientists, NGOs, community and so on. These are the representatives of the ethics committee who can be the saviour of the human rights of trial subjects.

### **Role of the Non-Governmental Organisations in Ethics Committee**

NGOs fight for human rights not only in India but also in many countries. In clinical trial also NGO's can act as the role player in the protection of rights of the trial subjects. This is also legally made possible through the constitution of ethics committees with the presence of NGO participation. The mere representation of an NGO member will not make the process of protocol review impartial and fair. The very nature of review of protocol and the monitoring of trial will be creating many technical barriers. The medical terminology used, side effects of drugs and even the very nature of components included in a trial drug cannot be easily identified by the representative of the NGO. This can only be possible by the inclusion of a trained and knowledgeable person as an NGO representative. Law either failed to foresee this aspect or resolutely avoided the same. The Indian law does not prescribe the

method through which the ethics committee is to be elected. In most cases the institution will include a person to favour their interest as an NGO representative.

This dilemma can be overcome by few amendments to the existing law. The state shall maintain a list of qualified NGO's or social scientists having adequate qualification and knowledge about human rights, medicine, and side effects of various chemical compounds. This standard should also be introduced internationally. The United Nations Organization, World Medical Association and Red Cross Society can organise awareness programs or short term courses for educating these values. NGO members vote should be made crucial in deciding the fate of the trials and the national authorities like Drugs Control General of India should always keep a rapport with these NGO members of various ethics committees. The relevance of NGO intervention in clinical trial can be easily learned from the recent Indian experiences. The impact of unethical trials is brought to the notice of Indian Supreme Court by certain NGO's. Apart from the review of protocol, trained NGO's and their representatives can make the consent taking procedure more consistent and reasonable. NGO's role thus should be positively designed so as to enhance the human rights of trial subjects in clinical trials. NGO's can become a balancing factor against the excessive economic and professional interest of medical community.

## **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 wellbeing of patient community.<sup>47</sup> 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

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<sup>47</sup> MARK DAVIES, *MEDICAL SELF-REGULATION* 90 (Ashgate Publishing Company 2007).

of safety of her illiterate patient community. Looking back, the doctrine will appear as a contribution of judiciary 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.<sup>48</sup> In short, the doctrine in its present form cannot tackle the vulnerable position of trial subjects. Even the presence of strong research ethics committee cannot make the situation better. A codified piece of norms on informed consent and its rigid compliance is highly required.

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<sup>48</sup> SHAUN D. PATTINSON, *MEDICAL LAW AND ETHICS* 369 (Sweet and Maxwell 2006).