ANALYSING CLINICAL RESEARCH/TRIALS IN INDIA: A LEGAL PERSPECTIVE

Shikhar Sthapak [*] *& Pragalbhi Joshi* [**]

ABSTRACT

Clinical research or trials under Rule 122 of DAA of Drugs & Cosmetics Rules, 1945 is clearly defined as, "*systematic study of new drug(s) in human subject(s) to generate data for discovering and/or verifying the clinical, pharmacological and/or adverse effects with the objective of determining safety and/or efficacy of the new drug*". The needs of Pharmaceutical Industry around the world have been increasing very swiftly; thereby, making India a global hub for outsourcing. The recent upsurge in the clinical trials conducted in the country can be accredited to: poor and illiterate people volunteering without an informed consent, alteration in the Intellectual property regimen after WTO pact and cheap labour cost. Instead of altruistic or philanthropic motives, the main ideological bedrock of the rise of clinical research/trial in India is the maximisation of profits, by putting onus upon the interest of poor people. Across the globe, there are various standard scales and treaties through which clinical trials are controlled and regulated, where as in India, these trials are regulated and supervised under Schedule Y of Drugs and Cosmetic Act, 1940, which are supervised by office of Drug Controller General of India (DCGI). The paper analyses the applicability of Article 21 and effect in the context of clinical research/trials. In this paper, the authors will scrutinise and study the importance and procedures of conducting the clinical research/trials and also, the various regulations and committees formed to monitor the conduct of the clinical research/trials in the wake of the events that happened in the recent past. Moreover, the Supreme Court in a PIL also stated that the trials will be done only under the supervision of Health Secretary. A country like India where there is multi-cultural attitude and varying healthcare standards, there is a greater need to pay attention to ethics, to make it a leading realm in Good Clinical Research.

Keywords: Clinical Trials Regulations; Drugs and Cosmetic Act, 1940; Intellectual Property;

[*] BBA. LLB.(Hons.), National Law University Odisha
[**] BBA. LLB.(Hons.), National Law University Odisha

Pharmaceutical Companies; Ethics.

INTRODUCTION

Clinical trial(s) is defined as, "systematic study of new drug(s) in human subject(s) to generate data for discovering and/or verifying the clinical, pharmacological and/or adverse effects with the objective of determining safety and/or efficacy of the new drug".[1] The trials of these pharmaceuticals products are conducted on human subjects after its pre-clinical trials to discover/or verify whether these products can be used for public at large without causing adverse effects and with efficacious results. Many factors lead India to become a global hub for clinical trials, which has both its positive and negative points; leading to the rising concerns among different section of society.

To gain an insight on how the clinical trials are conducted a design of pilot experiments are developed. The success of a trial depends on the effectiveness of how the treatment has worked in practicality, and the efficacy is how well it has responded during the trials. These trials are a significant boost to the economic conditions of under-developed countries like India, since on one clinical trial process millions of dollars are spent by the pharmaceutical companies.

Through this paper, the writer wants to discuss what are the standard procedures which are followed by the pharmaceutical companies in conducting these trials in Indian, and how are they being regulated & implemented throughout the boundary of India. Also, the horizon of this paper will be expanded to discuss the merits & de-merits of these trials and the regulations governing them. Several events that happened in the recent past would also be discussed in the due course, like: the reports by expert committees, ruling by different courts in India, International Treaties.

CLINICAL TRIAL-EMERGENCE AND IMPACT

Research on human subject conducted in the laboratories, after conducting pre-clinical trials[2] on animals/in vitro, in vivo & ex vivo for establishing a new drug which is both safe and efficacious on using it, is generally known as clinical research/ trials. Research in the area of

[1]The Drugs & Cosmetic Rules, 1945, Rule 122.

[2]Monograph, TILEM, NLSIU Bangalore, Vol. 1 ed. (2010); b*efore testing on Human Subjects begin, an extensive laboratory research must be done on the animals*.

drug leads to the discovery newer, safer & more effective drugs; and to est. a new drug in the country, only clinical trials can achieve it.[3] On considering the position of India, a new drug can only be introduced in the market after its laboratory trials with the safeguards 'cause of the varying health-care standards & multi-cultural approach present in the country; also making it necessary to pay greater attention to professional ethics to give rise to good clinical practice.

REASONS FOR THE UPSURGE IN CLINICAL TRIALS

The first ever trial was done by James Lind's to demonstrate that the citrus fruits cure scurvy.[4] Clinical trial in India is not a new concept to be developed in India. CharakaSamhita (medicine, 200 B.C.) &SushrutaSamhita (surgery, 200 A.D.) are the two ancient scripts, which shows that the medical research in India is not something new, but a lot has changed. But, this sudden upsurge in the clinical trials in the Asian continent and esp. in India can be attributed to the following three main reasons:

1. Poor & Illiterate rate in India- Since, India is country where the majority of the population is living under poverty and are illiterate; therefore the need for material resources is very high in this section of society. People, here, willing accept the money that is given to them for conducting these trials on them, without being properly informed about the intricacies involved in the process. Their consent is obtained either on false promised/ benefit or without being fully informed about the risk involved.
2. Cheap labour- In India, due to the large population living in poverty and illiteracy, the labour rate in India is very cheap as compared to other countries, which have better human development index. To earn money through any means, the population accepts whatever is given to them, leading to their exploitation on false grounds and incomplete information.
3. Alteration in Intellectual Property regime after WTO pact- India on becoming a member of the WTO in 1995, agreed to adhere to the product patent regime in 2005;

[3] *Critical note on Clinical Trials*, Ministry of Health and Family Welfare, Govt. of India, *available at* http://www.mohfw.nic.in/.

[4] Simon, Harvey B, *The Harvard Medical School guide to men's health*, New York, ed. 1st, pg. 31 (2002).

resulting into rights of the pharmaceutical company to process products and patent it in India, making it as a favourable destination for conducting global clinical trials.[5]

These above points are the main reasons for the upsurge in clinical trials in India. But, for these trials a standard procedure shall be adopted that, the consent obtained shall be informed consent i.e., the subject shall be informed about the adverse effects of the trials to be conducted, they shall not be lured by money, or any other monetary benefits, etc.

EFFECTS DUE TO CLINICAL TRIALS ON PEOPLE

There are provisions for regulating and ensuring quality, safety & efficacy of drugs to reduce the adverse effects caused by these trials, still, their implementation is not done properly, hence leaving scope for the exploiter to take advantage over the poor & illiterate people and exploit them by luring them into false benefits. The effects of a clinical trial with positive execution and effects are:

1. Chance of surviving of the patient if the drug is successful increases.
2. If, the results of the test show positive effects, then a new & safer drug could be introduced in the country.
3. It also helps in boosting the economic strength & self-dependency of the country.

Whereas, if the necessary safeguards required for the trials are not followed, then the negative effects are:

1. In adverse situation, death of the human subject could be caused.
2. Can also result into injuries for life.
3. Disturbs the family life of the person.

The effects of these clinical trials whether good or bad, depends upon the standard of procedure followed by the people involved in conducting these test on human subject. If the procedure that was followed during the test is found out to be incoherent with the standard procedure, then it leads to the violation human rights and hence, violation of Article 21 of the Indian Constitution[6]. This right against violation is the fundamental right of any citizen of India, which shall not be violated/ breached at any given point of time.

[5]P.K Julka, *Clinical Trials in India: Dilemmas for developing countries* (April 2007), *available at* http://www.ecronacunova.com/pdf/whitepapers/Whitepaper-CT%20in%20India.pdf.
[6]The Indian Constitution, 1950, Art. 21- Protection of life and personal liberty.

EXPERTS COMMITTEES FOR CLINICAL TRIALS

For looking into the implementation of the procedure laid down in the Drugs & Cosmetic Act and the ethics followed in the clinical trials, various expert committees were formed to draft its recommendation on this subject-matter. Experts committees formed were:

1. MASHELKAR EXPERT COMMITTEE (1999) - This committee identified that, clinical research in the country has an immense growth potential. The committee has suggested for basic change in legislation, allowing for import of animals, contract research & a legal status for institutional ethics committee. Also, it recommended for establishment and operationalization of cGMP, GLP & GCP monitoring authority.[7]

2. PROF. RANJIT ROY CHAUDHURY EXPERT COMMITTEE (2013) – This committee was constituted to formulate the policy and guidelines for approval of a new drug/ or banning any drug & clinical trials. Various recommendations that were given by this committee are as follows:

   a. Planning of a transparent and equitable system of clinical evaluation of new drugs.
   b. A Central Accreditation Council should be set up to oversee the accreditation of institutes, clinical investigators and institutional ethics committees.
   c. Clinical trials to be conducted at only accredited centre.
   d. A broad expertise-based Technical Review Committee (TRC) to ensure speedy clearance of applications without compromising on quality of data and rules and regulations, and many more.[8]

These were the few recommendations made by the expert committees on the growth, procedure and guideline followed in conducting clinical trials.

PROCEDURES AND REGULATIONS RELATING TO CLINICAL TRIALS

A. PHASES OF CLINICAL TRIALS

Clinical trials on Human beings are executed in Four Phases. If the drug can successfully pass

[7] *Supra* note 6.

[8] Prof. Ranjit Roy Chaudhury Expert Committee Report, *To formulate policy and guidelines for approval of new drugs, clinical trials and banning of drugs*, Ministry of Health and Family Welfare, Govt. of India (July 2013).

through the Phases I, II, and III, it is usually approved for use in general population.

Precedent to the trials on drug extensions drugs Pharmaceuticals Companies pre-clinical studies are conducted. The Phases are conducted as per the guidelines of the National Institute of Health:

Phase I: A small group of 20-80 healthy volunteers are tested for a new biomedical intervention in a small group of people, to evaluate a safe dosage range, and to identify side effects.

Phase II: A larger group of several hundred is subjected to clinical trials study the biomedical or behavioural intervention to determine efficacy and to further evaluate its safety.

Phase III: Studies investigate the efficacy of the biomedical or behavioural intervention in large groups of human subjects by comparing the intervention to other medicines as well as to monitor adverse effects, and to collect information that will allow the intervention to be used safely.[9]

Phase IV: Studies are conducted after the intervention has been marketed and approved by DGCI. These studies are designed to monitor effectiveness of the approved intervention in the general population and feedback is taken.[10][11]

B. INTERNATIONAL REGULATIONS TO GOVERN CLINICAL TRIALS

The principle*primum non nocere*[12] is important in the domain of human rights and has time and again encapsulated in medicine law.[13] Clinical/drug trials have repeatedly come up in historical and contemporary debates on this theme. Ethical obligations have been shunned since the time of Nazis by the physicians in response to "national threat".[14] Various

[9]Highlight Health, *New drug failure rates rising in Phase II and Phase III clinical trials* (Sept. 2nd, 2014), *available at* http://medcitynews.com/2011/06/new-drug-failure-rates-rising-in-phase-ii-and-iii-clinical-trials.

[10]*Clinical Trials in India: Issues and Concerns* (Aug 31st, 2014) a*vailableat* http://www.legaltrigger.com/articles/16.pdf.

[11]AnkurPaliwal, *Ethics on Trial*, Down to Earth (Aug 31st, 2014), *available at* http://www.downtoearth.org.in/content/ethics-trial.

[12]Merriam-Webster Online Dictionary, (September 1st, 2014) *available at* http://www.merriam-webster.com/dictionary/primum%20non%20nocere), *Primum non nocere- The first thing is to do no harm*.

[13]Delon Human &Sev S. Fluss, *The World Medical Association's Declaration of Helsinki: Historical and Contemporary Perspective*, (August 30th, 2014) available at http://www.wma.net/en/20activities/10ethics/10helsinki/draft_historical_contemporary_perspectives.pdf.

[14]Mustafa Khidir Mustafa Elnimeiri, *Nuremberg Code: A Landmark Document on Medical Research Ethics*,

declarations and codes have evolved to regulate medical experimentation.

1. THE NUREMBERG CODE

It was the first International instrument, though not binding, on Ethics of medical research due to the Cruel experiments of Doctors on the Prisoners. In the Code, the principle 1 reflects the importance of voluntary consent which is non-negotiable.[15] The same principle has threefold implication. Firstly, the participant has the legal capacity to give consent. Secondly, such consent should be voluntary and free, and not a by-product of force, coercion, fraud, deceit, duress, etc. Thirdly, such consent should be an exercise of informed choice, involving "sufficient knowledge and comprehension about the subject-matter"[16].The remaining provisions deal with the dimensions of clinical trial, the design of the experiment, expected outcomes and risk mitigation,prohibiting an experiment wherever a strong likelihood of disability or death exists,adequacy of preparation, facilities, quality of risk control equipmentand the obligation of the researcher to terminate the experiment if required.[17]

2. THE DECLARATION OF HELSINKI, 1964

It was the next worldwide document involving human research protection and went through six amendments, the one used currently was the one amended in 2008.[18] The World Medical Association developed the Declaration of Helsinki as it had three categories: principles concerning obligations of the physician[19], principles of consent[20], transparency to bring about effective regulation in clinical trials.[21] Principle 17 also mandates the consent of legal representative, has to be given wherever possible. These have been accepted as a uniform standard of ethics that are applicable to trials.[22]

3(2) Sudanese Journal of Public Health 94 (2008).

[15]The Nuremberg Code, 1947, Principle 1.

[16]*Supra* note 22.

[17]*Supra* note 23, Principle 2, 3, 4, 7, & 10.

[18]World Medical Association, *Declaration of Helsinki* (September 3rd, 2014), *available at* http://www.wma.net/en/30publications/10policies/b3/, (adopted at the 18th General Assembly in Helsinki, Finland).

[19]The Declaration of Helsinki, 1964, Principles 3, 4, 6, 23 & 24.

[20]*Ibid.* Principles 9, 17, 26, 27 & 28.

[21]*Supra* note 27, Principle 19

[22]Delon Human &Sev S. Fluss, *The World Medical Association's Declaration of Helsinki, Historical and Contemporary Perspective* (Sept. 1st, 2014), available at http://www.wma.net/en/20activities/10ethics/10helsinki/draft_historical_contemporary_perspectives.pdf.

3. INTERNATIONAL ETHICAL GUIDELINES FOR BIOMEDICAL RESEARCH INVOLVING HUMAN SUBJECTS

The Council for International Organizations of Medical Sciences ('CIOMS') along with the World Health Organisation prepared guidelines. This declaration highlighted on the ethical principles to conduct biomedical research on human subjects could be applied to in developing countries.[23] Depending on circumstances, the guidelines change; but the structure remains unaltered. The 2002 amended version can be classified into those governing consent (Guidelines 4 and 5) and the ones to govern vulnerable groups i.*e.*, Guideline 14, 15, 16 and 17.Guideline 4 is a reiteration of the principles engraved in Declaration of Helsinki.

Guideline 16 serves to prevent gender discrimination as well. Thus Guideline 16 confirms the right to self-determination of a woman. There are a number of Important Documents and Codes worldwide to regulate human rights in the context of health law.

C. LAWS RELATING TO CLINICAL TRIALS IN INDIA

Clinical research industry in India is still in its initial stage. Therefore, the mechanisms are also at the development phase. The DCGI's approval is required by submitting relevant information with regard to trial.[24] The Schedule Y of the Drugs and Cosmetics Rules, 1945 deal with clinical trials. Schedule Y can be divided into three categories: the first deals with application procedure, explanation of Phase III trials and the responsibilities entrusted on sponsors and ethics committees. The second with Informed consent given in Schedule Y provides a free, informed and written consent. Legal representation is required from those participants void of legal capacity. Rule 2(4) and Appendix V read together is an exhaustive source for consent under the present rules. Appendix V lays down the checklist for the elements of the informed consent document. The third is with regard to studies done on special groups.

Rule 3 deals with ageing people, children, and pregnant women.It defines the circumstances under which recruiting subjects from vulnerable or special groups are justified. The 2013 amendment to rules gives Rule122-DAB lays down for financial compensation in case of

[23]CIOMS & WHO, *Council for International Organisations of Medical Sciences* (Sept. 2nd, 2014) *available at* http://www.cioms.ch/.

[24]BallariBrahmachari, Melanie Fernandes&Arun Bhatt, *Pharmacovigilance for Clinical Trials in India: Current Practice and Areas for Reform* (Aug 31st, 2014) pg. 49–53, *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3121263/?tool=pubmed.

injury sustained by the subject during trial.[25] Rule 122-DAC provides for pre-requisites to be considered, when granting permission.[26] Additional conditions may also be specified. Rule 122 DD specifies mandatory registration with Ethics Committee.[27]

The ICMR issued the Ethical Guidelines for Biomedical Research on Human Participants. In the event that human subjects are used, other principles such as those of free informed consent, non-exploitation, accountability and transparency gain prominence.[28] These were guidelines suited for the Indian scenario. Chapter II builds on the basic responsibilities of the Ethics committee as well as their, regulation, decision making process, training, monitoring, and review procedures. Chapter III of the Guidelines deals with general ethical issues, the important ones discussed herein are- voluntarily consented, selection of vulnerable groups as human participants, and compensation. The Guidelines allow for non-written documentation of consent,if the participant is willing to or is unable to communicate his consent in writing in contrast to the corresponding provision in Schedule Y where the only acceptable form of consent is written. The Section 336 of the Indian Penal Code provides for anyone who rashly or negligently endangers human life or safety. Punishment for the same has also been included in the said Section.[29]

It was also held in PIL heard by the Supreme Court that, any clinical trial that is being conducted in India should be done in accordance with the prescribed procedure under Schedule Y under the supervision of the Secretary, Health & Family Welfare.[30]

D. ANALYSIS OF THE ABOVE LAWS

One of the most challenging-part of such trials is to check the exploitation of vulnerable parties.[31] Firstly, individual consent differs in societies. Like in China and Pakistan, for the VIPS programme it was necessary to seek the approval of the religious leaders before the guardians. The only form provided in Schedule Y is a written one, and India being a country with low literacy levels faces problems in that. ICMR provides ways on consenting, but then

[25]Vide Notification of the Government of India, Ministry of Health and Family Welfare (Department of Health) No. G.S.R 53(E), (30th Jan 2013), The Gazette of India.

[26]*Ibid.* No. G.S.R 63(E) (1st Feb 2013), The Gazette of India.

[27]*Ibid.* No. G.S.R 72(E) (8th Feb 2013), The Gazette of India.

[28]AshnaAshesh&Zubin Dash, *Inadequacies in Clinical Trials In India* (Aug 29th, 2014), NUJS Law Review, *available at*<http://www.nujslawreview.org/pdf/articles/2012_3/05_ashna_&_zubin.pdf>.

[29]*Ibid.*

[30]SwasthyaAdhikarManch, Indore vs. Union of India, W.P. (C) No. 33/2012.

[31]Ravindran P. Clinical trial on trial, *available at*<www.thehindubusinessline.com> (5th September, 2014).

they do not have binding effect.[32] Secondly, problems arise due to different perceptions about health and disease, the confusion between research and therapeutic context and the kind of study (placebo, randomisation and vaccine failure). Fourthly, social complexities inhabit the participant if he gets a disease that might be considered a taboo, ex. AIDS. The confidentiality clause has adverse effects.

Scientific misconduct is a problem across the globe. In US, the FDA has increased surveillance over clinical trials to make them adapt to Good Clinical Practices. India also needs to practice the same with stricter norms and procedures.[33] Recently, in a district In Andhra Pradesh, phase III trials were done only on the basis of thumb impressions by hostel wardens. Right to health is a fundamental right. These instances show the gross failure of justice and consideration of human rights in medical testing arena. A number of regulations have been on the charts for some-time, but speedy implementation, proper administration and monitory mechanism is the need of the hour. Ethics Committee forum shopping is now a common phenomenon.[34] The absence of periodic being binding, it becomes an optional procedure. The law only gives the duties of ethics committees.[35] The term "appropriate" is not defined. If hospital authorities form a part of ethics committee, conflict shall arise in a way that rules hall be flouted. In case of Serious Adverse Event, it has to be reported within seven working days, which is too lenient.[36]

E. COMPENSATING THE VICTIMISED

Forum for Ethics Committees in India, Indian Society for Clinical Research and ICMR had issued Draft Guidelines for Compensation to Participants for Research Related Injury in India in 2008 to apply to all types of clinical research.[37] The 3rd Amendment in 2011, in Drugs and

[32] Morioka J. Clinical trials in China: today and tomorrow, *available at* <www.csemagazine.com> (4th September, 2014).

[33] P.K. Jhulka, Clinical Trials In India: Dilemmas for Developing Countries, available at http://www.ecronacunova.com/pdf/whitepapers/Whitepaper-CT%20in%20India.pdf (5th September, 2014).

[34] AnkurPaliwal, *Ethics on Trial*, Down to Earth (Aug 31st, 2014), *available at* http://www.downtoearth.org.in/content/ethics-trial.

[35] Schedule Y "EC(s) should make, at appropriate intervals, an on-going review of the trials for which they review the protocol(s)".

[36] The Drugs and Cosmetics Rules, 1945, Schedule Y, Appendix VII.

[37] Sinha K, *New norms for clinical trial-related injury soon*. TNN Nov 25, 2011, *available at*<http://articles.timesofindia.indiatimes.com/2011-11-25/india/30440355_1_clinical-research-research-related-injuries-clinical-trials>.

Cosmetic Rules, 1945 introduced rules for "compensation in case injury or death during clinical trial"[38].

1. PRINCIPLE OF 'NO-FAULT COMPENSATION'

Unlike the "tort liability" here, the trial participant need not prove that he suffered the loss as a result of his participation.[39] It is better in a country like India, since blame is not put off on anyone. It is also beneficial where injuries are independent of negligence. It helps the investigator also. Since, he decides the compensation on the basis of previous medical history, age, etc.

2. INFORMED CONSENT

Informed consent document respects the decision. However, harm is unknown; and more importantly in India people are not generally aware of their rights, there might exist some theoretic misconceptions also .This make the trial a challenge.[40]

3. INSURANCE

The Sponsor here decides the insurance cover and the premium to be paid. A number of things like-the size of the trial, the phase, degree of risk, financial capacity of the conducing company ,type of drug being tested, demographic profile of the group. It is a part of informed consent. So, awareness that such a right exists, is important. The Participants should be insured against adverse events. The results cannot be mitigated, the harm cannot be undone. But, they can be compensated at least.[41]

4. WHAT IS COMPENSATED?

In case of research injury, the CDSCO draft rules provide for insurance it can be due to:

---

[38]Ministry of Health and Family Welfare, Government of India. The Drugs and Cosmetics (3rd Amendment) Rules, 2011.Ministry of Health and Family Welfare in the Gazette of India Extraordinary, Part II-Section 3(i), *available at*http://cdsco.nic.in/html/compensation_during_clinicaltrial.pdf.

[39]Elliott C, *Justice for Injured Research Subjects*. N Eng. J Med. 2012:367:6–8.

[40]Bhatt A, *Government's role in shaping public perceptions about clinical research*, PerspectClin Res. 2012; 3:87–9.

[41]Sinha S, *Clinical trial insurance comes to the aid of Pharma companies*, Economic Times- Aug 12, 2008, *availableat*http://articles.economictimes.indiatimes.com/2008-08-12/news/27727690_1_clinical-trial-drugs-clinical-research-organization.

- Adverse effects of the investigational product/s.
- Departure from approved protocol, scientific misconduct or negligence by the Investigator/Sponsor/ CRO.
- Failure of an investigational product to provide intended therapeutic effect.
- Administration of placebo providing no therapeutic benefits.
- Adverse effects due to concomitant medications.
- Compensation to be paid to a child injured *in utero* through the participation of the parent in a clinical trial.[42]

5. HOW MUCH TO COMPENSATE?

The draft rules provide that Ethics Committee should compensate within 30 days of the matter being referred to. If there is no formal claim, the Committee reviews the Serious Adverse Event. It considers a few parameters, they are:

a. Age of the deceased
b. Income of the deceased
c. Seriousness and severity of the disease, the subject was suffering at the time of his/her participation into the trial and
d. Percentage of permanent disability

They have also provided for a formula to calculate the compensation in trial related death. However, the problem here is, how can the Committee calculate the "percentage disability". The document mentions psychological/emotional injury, but how can they be quantified.

CONCLUSION AND SUGGESTIONS

With better regulations, clinical development can get a stronghold in the global platform. However, the government has amended the Drugs and Cosmetics Rules in 2013 to provide for compensation in case of fatalities during clinical trial. But, the problem with the current legislation is that does not recognise the human rights. It does not see humans as individuals with their rights. Individual rights are shoved off for the greater good. Also, India lacks thorough legislation and implementation of such laws. The government in the process of

[42] *Supra* note 38.

welfare has forgotten the human rights. Also, if the given drug is found effective, they should be provided at subsidised rates or for free to the participants. The confidentiality clause needs to be reviewed. Since, some diseases incurred from trials lead to social stigma, in which case drug details should be made public. In case the trial involves higher risk, an intense review should be conducted. The Government has taken a number of steps to guarantee the rights of the participants in the clinical trials, but they also suffer from a few loopholes which need attention; given the context of the recent happenings. There still exist a few drawbacks in the compensation/insurance scheme introduced by the Government. Only when they are done with, can the smooth and proper functioning of the new rules for compensation be established. The victims in trials should be compensated with the losses incurred. Litigation costs should be cut down. The parameters for compensation need to be worked upon. It is time the medical profession became more responsible about its ultimate duty, i.e. to protect an individual; not to harm him in the process.

BIBLIOGRAPHY

- The Drugs & Cosmetic Rules, 1945.
- Monograph, TILEM, NLSIU Bangalore.
- *Critical note on Clinical Trials*, Ministry of Health and Family Welfare, Govt. of India.
- Simon, Harvey B, *The Harvard Medical School guide to men's health*, New York.
- P.K Julka, *Clinical Trials in India: Dilemmas for developing countries*.
- The Indian Constitution, 1950.
- Prof. Ranjit Roy Chaudhury Expert Committee Report, Ministry of Health and Family Welfare, Govt. of India.
- Highlight Health, *New drug failure rates rising in Phase II and Phase III clinical trials*.
- *Clinical Trials in India: Issues and Concerns*.
- AnkurPaliwal, *Ethics on Trial*, Down to Earth.
- Merriam-Webster Online Dictionary.
- Delon Human &Sev S. Fluss, *The World Medical Association's Declaration of Helsinki: Historical and Contemporary Perspective*.
- Mustafa Khidir Mustafa Elnimeiri, *Nuremberg Code: A Landmark Document on*

Medical Research Ethics.

- The Nuremberg Code, 1947.
- World Medical Association, *Declaration of Helsinki*.
- The Declaration of Helsinki, 1964.
- CIOMS & WHO, *Council for International Organisations of Medical Sciences*.
- BallariBrahmachari, Melanie Fernandes&Arun Bhatt, *Pharmacovigilance for Clinical Trials in India: Current Practice and Areas for Reform*.
- The Gazette of India, Vide Notification of the Government of India, Ministry of Health and Family Welfare (Department of Health).
- The Drugs and Cosmetics (3rd Amendment) Rules, 2011.Ministry of Health and Family Welfare.
- AshnaAshesh&Zubin Dash, *Inadequacies in Clinical Trials in India*, NUJS Law Review.
- SwasthyaAdhikarManch, Indore vs. Union of India, W.P. (C) No. 33/2012.
- Ravindran P. Clinical trial on trial.
- Morioka J. Clinical trials in China: today and tomorrow.
- AnkurPaliwal, *Ethics on Trial*, Down to Earth.
- Elliott C, *Justice for Injured Research Subjects*.
- Bhatt A, *Government's role in shaping public perceptions about clinical research*.
- Sinha S, *Clinical trial insurance comes to the aid of Pharma companies*.