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Man has been confronting with the meanness of nature and tried to overcome all type of disasters. As civilization progressed, man had to encounter many ailments caused by both external and internal factors. So he initiated research for new and advanced medicines and had to design and prepare therapeutic and preventive medicine. It would be the beginnings of medicine and a thought that of health care concerns itself that started using human beings in medical research.

Experimenting medical products on human beings became essential and important for medical progress and advancement of the health related concerns of the society. All medical experimentations are framed and formulated to collect necessary information or evidences for the authorities, institutions, and researchers. They analyse the safety and efficacy of medical products through various experimentations to ascertain whether it is safe for consumption or whether it has the potential to alleviate various ailments.

Human beings started to search for medicines with herbal combinations. Many herbal products proved good to treat many diseases of human beings. Natural products like menthol, extracted from peppermint were extensively used for the treatment of coughs and cold. A search for improved system of therapy by identifying, accumulating and storing natural herbs in a dried form was very common.

Boneset tea was commonly used as a cure for fever; peppermint very much cured and relived a paining tooth or a sick baby. Early challenges were to find out a combination of medicines that are effective and with quality. The quality of drug often varied with the raw materials or skill of the pharmacist.

Since centuries medical research has contributed very much to society and mankind. With the passage of time it became imperative to determine the true effects of any medical intervention before it is administered in patients. Here comes the relevancy of testing the newly introduced formula of medicine in the same specious where it needs to be administered.
With the advent of time the realization that the protection of basic human rights are essential for anyone living in a civilized society for freedom, justice and peace, triggered the employing of ethical and moral principles in every facets of medical intervention.

Health care sector is one among the ever developing sector of Indian economy because of growing population, diseases and increased awareness level. A government which protects the rights of its citizens need to see that the manufactures of the medicines need to guarantee the effectiveness of medicines and safety of the research participants. Health of an individual is the basis of all activities. The right of an individual imposes a correlative duty and casts a duty on the state, government or authority to safeguard those rights.

Generic drug industry leads the pharmaceutical sector in India. Around 75% of the medicines in India are generic drug which has contributed much to reduce the prices. Taking advantage from this low manufacturing cost, many companies exports the medicines to many developed countries. It has been reported that India has become the biggest supplier of medicines to the health care programs initiated by United Nations.

The health may be defined as an overall wellbeing of an individual. There are several factors which influence health, both internal and external. Mere absence of any disease does not mean that the person is healthy. This definition may be given a wider interpretation by giving the term health to mean, the strength to form a useful and beneficial creative life socially and economically.

This definition helps to expand the health thinking beyond a limited domain to a more humanitarian perspective. It widens the responsibilities of health professionals and their relationships with the people who come in contact with the health care sector.

Taking into consideration the fulfilment of MDG goals, many recommendable health successes were achieved from coordinated actions of public and private sectors and civil society. There are many pharmaceutical companies which aims not only economic advantages but also to strengthen health system and also to improve health of the marginalized and the vulnerable poor.

To answer the call of UN to build up a responsible business and civil society the research-
based pharmaceutical companies are in need of proper legal framework to improve the life of the patients worldwide.

From time immemorial it is a common practice that to entrust the duty of decision making relating to the patients to the doctors. This paternalistic approach has gradually been changed by promoting patient individuality and autonomy, whereby patients and doctors share the decision-making responsibility. As a result the relationship of the physician and the patient turned to be entirely different than what it was earlier. Conflicts still exists in medical community to correctly demark the duties, rights and privileges of both the health care seeker and the physicians. It turns to be more problematic and complex as the physician takes the role of a researcher.

**Common perception of victimization during medical research**

Only if the questions of how victimization occurs in the name of medical research, how commonly it happens, what are the limitations involved in getting accurate knowledge of the procedure of medical research ,how to overcome these limitations etc are answered the issues may be understood in a much better effective manner. Even with tremendous developments has been made in the humanitarian and human rights fields, none of these questions are answered.

There are many instances of victimization of research participants of which most of them are vulnerable. Medical research is an essential factor for the progress of medical science and thereby for benefitting the future generation. But where to specify the demarcation of scientific development and protection of rights of the individual research participants is to be identified.

History reveals that prisoners, children, elderly, racial minorities and women are victimized under the cover of medical research and advancements of science for welfare of humanity at large. Utilizing a research subject who does not have the medical condition which the researcher is addressing is a clear cut violation of right to his life and personal liberty even if it brings beneficial results for the public.
An informed consent form with no clear and complete explanation is fraudulent suppression of material facts. Such suppression of material facts results in victimization.

In medical research involving human beings the victims are usually vulnerable people. In Ericka Grimes’s case, a non therapeutic experimentation was conducted for ascertaining how efficient uncertain amount of lead paint abatement procedure. Research department carrying out the experimentation aided the landlords to give their premises on rent to families with young healthy children.

The child was asked to remain in the houses as continued presence of the research subject was needed for the study. Accurate, complete and clear description was not revealed while making the consent agreement and signed by the parents of the children. They were not given full information of how the experimentation is going to be carried out and designed. Before conducting this study the same research institute had already initiated a study which revealed that frequent contact to dust consisting of lead is hazardous for children.

Even after conducting this study and knowing the research results researchers act of keeping the minors intentionally in a potentially dangerous surroundings where there is no treatment or medicinal advantages to that particular child may be categorized as victimizing the research subjects. In such instances, consent given by the parent, no matter how informed, is insufficient.

The ulterior intent behind safeguarding the basic rights of the research participants is guarantying an appropriate and a generally accepted standard of living. Whatever be the ethical and moral justifications no one wants to sacrifice their life even if it is for the benefit of the humanity at large.

The principle and theory of informed consent is considered as cornerstone of consumers in the field of health scenario. Development of medical science and experimentations and research has always gone hand in hand. The dignity and privacy, the basic rights of the patients need to be protected and promoted along with the advancement of medical science. The terms biomedical research and medical experiments are used as if same meaning and are
known as medical research. The terms clinical trials, clinical research also means medical research.

Medical research facilitates to find out better and improved treatment from the presently available medicines, as well as results in the advancement of new and improved therapy for certain ailments for which there is no treatment currently available. Before administering or experimenting a new medicine on human being, animal studies are being conducted.

The UK is considered as the pioneer and much advanced in carrying out medical research involving human beings. Since the origin and development of the pharmaceutical industry many years back, more drug related studies, medical research etc were performed only in USA. Those researchers bestowed commendable role in several of the discovery leading to tremendous advancements that made a change in medical science and also in the manner of health care system.

Medical research is the foundation on which modern medical science is built. Medical research contributes to the economy of the country and provides the patients with several means of accessing new treatments before the medicine reaches for sale. Medical research as non therapeutic in nature demands greater responsibilities from the health professionals even when motivated with advancement of science or with the intention to identify the efficiency of a newly introduced drug.

The medical research is a method of understanding different procedures of effects of medicine on human beings. It has two essential functions and features like:

1. A working and ongoing function to identify whether the newly invented medicinal combination or process can effectively bring out anticipated advantages;

2. A security factor to find out the risks involved in the new procedure of medication, and to determine whether these risks are manageable.

It is essential to identify what research in medicine means? , what is its nature? What are its
purposes? Contemporary physicians often describe research as something done on behalf of
god to find out answers for those unanswered questions about new diseases for which no
medication is available.

Carrying out medical research is holy or God’s work, the result of which is miraculous and
good for everyone. This argument is subjected to many criticisms. A blind devotion produces
uncritical action that may ultimately destroy the values essential to human dignity. The
ultimate meaning and purposes of medical research is to rid men of diseases, to protect them
from maladies with which they are threatened, to relieve them of discomforts ones they are
establishediii.

The term medical research is having the same meaning as that of medical experimentation,
clinical research, clinical trials etc. The use of the term biomedical research is just an
adjective to denote the meaning of health related research as any research done with human
beings for identifying the efficacy of the newly introduced drug.

It was a Persian Researcher, Avicenna (Ibn Sina) who started medical research, clinical study,
experimentation, drug tests etc on human subjects. Before going into the definition of the
term medical experimentation, it is necessary to evaluate the meaning of the term research
subject.

**Specific Understanding of Medical Research and Research Subject**

The role of a doctor is different when he is acting as a physician and a researcher even when
the doctor and the person doing the research are the same individuals. The duties entrusted on
a physician are different from the duties of a researcher. The physician’s primary
responsibility is to provide therapeutic benefits to the particular patient and also to take care
of the matters concerning the health and welfare of any one approaching him.

The researcher’s primary duty and responsibility is accumulation and generation of
technological ideas for medical science. The chance for benefiting the research subject from
the research conducted on him is very rare. Thus the contribution of research towards the
research subject’s health and wellbeing is very much probable and not at all certain. It may
not bring therapeutic effects to that particular research subject.

There is a conflict based on the values underlying these two roles. The conflict revolves on the role played by the researcher and the doctor. It is not that much easy to make specific division among these roles. The functions of these two roles are very much interrelated. The main function is to alleviate illness. Here comes the importance of following the ethical requirements stipulated for the medical research.

A research subject is a human being volunteering in a medical experimentation and a recipient of the benefits of the products under investigation. The research subject may or may not be a healthy person. In most cases the research participants are selected on the criteria that the particular person has certain medical condition which is relevant in the progress of the medical research.

The federal guidelines relating to medical research involving human beings in US, a medical research is defined as an investigation or research conducted on a living human being for identifying the effectiveness of any particular medicine or a therapy\textsuperscript{iv}. Thus medical research is a process by which a research subject is subjected to various procedures to identify solutions to the research problems.

The preamble to the International Ethical Guidelines for the Biomedical Research Involving Human Subjects defines the term research as a process of actions formulated to mould or to form a generalizable knowledge. The Helsinki Declaration does not have a definition of the term research, but it points out the purposes for which a medical research may be conducted.

The term medical research includes, any experimentation in human participants with an objective to find out or identify the medicinal and pharmacological effects of the drug items, or to investigate and find out whether there is any unwanted after effects and outcomes to any of the investigational medicinal items and or to identify how it is being absorbed, how it has been distributed, the metabolic condition and the nature of excretion of any of the experimental medicinal items with the objective of ascertaining and certifying their secure
application and strengthen the efficacy.

Medical research is defined in Indian Good Clinical Practices designed by Central Drugs Standard Control Organization as, a study of the effects of pharmaceutical items on human beings – (whether who approaches the doctor for treatment or those who enrol for research purpose) – with a view to discover or identify the clinical, and pharmacological adverse reactions, for identifying their safety and / or efficacy.

Indian Good Clinical Practices defines document relating to medical research as, All records (including data which is written, documents which are preserved in the electronic, data preserved in a magnetic form or records in the optical forms, data received through scanning, x-rays etc.) that describe or keep the data of as preserved, to carry out and also for generating a result of the experimentation as well as the technique which need to be adopted.

The records consist of Protocol, records relating to the files stating permission given from the office of the DCGI, ethics committee, researchers, details, forms which requests consent, data of monitoring details, certificates of audit, letters that are relevant, reference ranges, data which is raw, completed CRFs and the final report.

**Medical Research v. Medical Practice.**

The border line between the medical research and the medical treatment may be clearly and definitely border lined. The main objective of the medical practice done by medical professionals is to bring some good or welfare to the patient. On the other hand, medical research is non therapeutic and does not presume to benefit or help in curing the ailment of the patient participant.

Research is carried out in the presumption of anticipated benefits that its outcome may bring benefits to future patients. In majority of cases the medical research is non therapeutic, only in minimum cases it aims at treating the research participant and to bring cure to his ailment.

The research subject’s ability to comprehend whether the physician is acting to treat his ailment or is experimenting the drug before him is very important. The role of the researcher falls somewhere between the basic medical scientist, biochemist, physiologist or the physician trained and skilled primarily in the treatment of the sick. Both deals with
acquiring new knowledge, both use the same types of laboratory procedures and methods of analysis.

The only difference is that the medical researcher who is trained as a physician applies the results of his investigation directly to the benefit of the patients. The researcher therefore performs a vital part in bringing elements of the fundamental science to the bedside with the physician.

An example of research that had a crucial effect on medical practice and that related to the doctors involving their patients who approach them for treatment in medical research as research participants is the Cardiac Arrhythmia Suppression Trial (CAST). The physicians were aware that cardiac death may cause as a result of ventricular arrhythmias. The said drug was widely used to reduce ventricular contractions which is premature in nature. It is medically assumed that any type of therapy for ventricular premature contractions with antiarrhythmic medicines may decrease mortality rate.

This medicine was administered on much number of patients and they received it with the hope of benefit. Finally, CAST was conducted in a wide range and it has been recorded as the medicine used to reduce cardiac death resulted in increasing the rate of mortality.

This report of the research study has commendably and tremendously increased and modified the practices and saved lives. This example emphasizes the crucial part of doctors taking care of their own patients and also involving in the task of advancement of knowledge and health care.

In medical research, researcher has the ultimate responsibility to ensure that the research subject is safe; the rights are protected and also need to consider the welfare of research participants of the experimentation and also to make certain that the members participating in the medical research follow all requirements for a valid research in an ethical way. The researcher plays a crucial role in formulating the research protocol or in making use of a design formulated by the sponsors of the research or others.

The researcher has certain key responsibilities for the conducting medical research ethically when it involves individuals below the age of maturity. To specify it clearly the research involving children, infants, adolescents etc. One among the prime responsibility of the person
conducting the research is to see that the subjects of the experimentation of this category achieve and maintain fruitful training, effectively.

The researcher need to be equipped to perform and invigilate all therapeutic and research process essential for the experimentation that involves children. Acquiring knowledge and carrying out the training effectively to confront the ethics and legal essentialities of initiating medical experimentation that includes children is another essential responsibility of the researcher.

There are specific standards for carrying out experimentation with minors. One of the prime responsibilities of the researcher is to guarantee that research protocols consisting of children abide to the criteria specified and accepted universally on the basis of ethical and scientific requirements pertinent for experimentation involving minors. Provide suggestions and modifications to the research protocol for a proper review and get sanction before starting or modifying medical experimentation.

Carry out the research in accordance with the protocol which has been approved. Revealing the possible interests that may come into conflict to appropriate parties. Safeguards need to be taken to see the procedures permission of the parents to be a part in medical experimentation.

It is also necessary to consider regulatory and ethical concerns as whether such standards are effective for carrying out the study. Specify the reasoning and suggest essential safeguards in accordance with laws if a waiver of permission of the parent is asked for. It is essential to communicate with children participating in research. There opinion needs to be considered in developing appropriate measures.

Proper information need to be provided as to the different stages of research and their role and the effect of research on the participant. Provide effective safety measures for ensuring and reporting of unwanted consequences. Violations of report protocols, defects, and issues as required to sponsors of the research or regulators. Revealing the results of the medical experimentation to the scientific community and to the society.

Demarking research and practice is also essential to determine the liability of the
researcher. The determination of liability is based on the fact that how much information the researcher has given to the research subject about the procedure in which he is involved. The use of an untested innovative procedure was termed as an experimental treatment, not as medical research or medical practice\textsuperscript{vii}.

The court gave approval to conduct a surgery or experimental treatment notwithstanding the fact that the procedure had never been tested on humans and its effects and risks were not known. Research consisting of human research participants may be differentiated from medical practice, health issues relating to rem and other modes and methods of to protect health issues that are formulated for making available directly to the communities.

The Practice is to treat with the success or result got through experimentation and it consists of diagnosis, preventive care or therapy. A research involves the systematic investigation and collection of data in order to evaluate the scientific validity of the proposed treatment. Research is to test a therapy, a new medicine, a procedure of conducting new and improved means and methods of therapy.

When a doctor practices medicine he may be committed to take care of their patients, reducing their sufferings, diminishing their sufferings and when a doctor acts as a researcher he may be dedicated to caring for the research, promoting knowledge for the advancement of science and for patients in future. There is always some possibility for these two commitments coming into conflict.

Professor Jay Katz, points out that regulations stipulating to furnish a proper informed consent from the research participant may fail. He opines that only if the researcher accepts this principle of informed consent as similarly as that of the Hippocratic responsibility the objective of safeguarding the individual rights through this doctrine may prove good.

He is also sceptical about accepting medical practice as a part of medical research. He opines that the obligation of the physician as that of a doctor and as that of a physician is totally
different. Physician’s obligation towards a research subject is much more than towards a patient.

A physician may take more care for the patients involved in medical research even when adhering to the terms of that particular research protocol. A researcher may correctly identify and describe roles and responsibilities when conducting human experimentation. It is a difficult task to differentiate research from treatment, doctors from scientists, or research participants from patients.

Jay Katz opines that in this encounter even though it is among two persons, in reality there are four persons involved in the procedure. The doctor, the researcher, the person who need immediate medical care and assistance, and the research participant who gins advantage from the said experimentation and also provide better medicines for their ailments to the future patients. In research there is a hope of learning rather than the expectation of success.

Giesen distinguishes research treatment and experimentation. Research treatment is to make use of better and advanced procedures for at least primarily therapeutic purposes.

Thus Giesen consider that the core to distinguish between medical research and therapy is the medical professional’s intention concerning the activities he is carrying out.

**Research with therapeutic effects Vs Research with non-therapeutic effects**

Therapeutic Research provides the members a chance to attain an experimental therapy that may prove advantageous (e.g. therapy with the drug under research). Non-therapeutic research aims at attainment of knowledge that may be for the welfare of generations to come but may not produce any beneficial effects to those actually involved in all procedures and goes through all the phases of medical research.

The differentiation made between therapeutic and that of research that are non therapeutic in nature is now considered by many physicians as without much help and substantially misleading. The use of a medicine is therapeutic if, a doctor may use an untested drug on a patient who has a particular ailment, believing the drug to be the best. Sometimes there may be only a hope of curing the disease.
The medicine is given for the benefit of that patient. On the contrary, if a doctor seeks healthy volunteers to test a drug’s possible side effects – the use is non-therapeutic. The medicine is not given to improve the volunteers health, but rather to test the medicine to see, whether it can be used on other people.

One illustration for this is that medical researches that consist of drugs consist of both elements, like therapeutic and non-therapeutic elements. In most cases the term therapeutic causes confusion as in the case of taking blood sample. In both cases the effect of the research may not bring a therapy that benefits and results in the welfare of the individual participant alone.

The European Convention on Human Rights and Biomedicine categorizes research relating to the benefit which arising to the research participant. ECHRB specifies that the outcome of the medical research may have the potential to initiate direct and appreciable benefit to the health of the research participant. Research may also aim at improving the scientific considerations on the person’s physical condition or ailments.

The end result of the research or the research outcome may have the capacity to benefit the society and to the individuals of the same age group or having the same ailment or consisting of the similar condition. Thus in essence ECHRB recognizes research with health benefits to the research participant and without health benefits to the participant.

In 2000 an amendment was made to the Declaration of Helsinki which amended the difference between ‘therapeutic’ and ‘non-therapeutic’ research. This difference was the main component feature of the Declaration since 1964. Now the Declaration envisages the fundamental principles of medical research consisting of human beings.

The declaration is also considered as an additional cover for medical experimentation connected with health care. Declaration provides that medical experimentation can be rationalized only when there is a justifiable expectation that the category on the medical research is carried out receives some advantages out of the said research.

A physician may join medical research with professional treatment or therapy, but the aim may be for acquiring new and improved scientific and medical knowledge advancements. A combination of medical research and treatment may be justified when it
proves good to the patient also by its prospective diagnostic or medicinal value\textsuperscript{xi}. When a person gives consent for a non-therapeutic research he may get only speculative psychological benefits acquiring from an altruistic act. He may not have any direct gain from the act.

At the same time, both the society and the researcher benefits from the act of consent given by the person for non-therapeutic research. Society gets medical advancements and the researcher gets advancements in this career.

The decision of a person whether or not to bring risk for himself for the welfare of society is very much a concern of morality. A balance may be maintained between risk for the particular research participant and the gain which researcher and the society anticipate from the research. The interest of every research subject may be protected as a human being with a right to dignity.

The preamble to the Convention on Human Rights and Biomedicine 1996, convinces the essentiality of respecting the human being from two different views, in the capacity of an individual and as an essential element of human race. It also acknowledges significance of guarantying personal dignity to each and every individual\textsuperscript{xii}.

The advancement of medical science and there by welfare and benefit to the society is an optional goal. He considers that it is not an uncompromising commitment. Freedom is entirely a first condition to be observed and surrendering of one’s body to research is totally against an enforceable social agreement. More importance may be given to the protection and freedom of the individual research subject than interest of the society.

The medical research which is indented to be conducted may be duly balanced against the case of not conducting it. It needs to be approved by an appropriate and eligible body of individuals who are outsiders to the said process involved in medical research. They may make a study and observe carefully may arrive at a certain suggestions that medical experimentation is essential to the progress of humanity and for the ecological and environmental welfare of the planet\textsuperscript{xiii}. The non-therapeutic research consists of many legal issues.
G.F. Tomossy and D.N. Weisstub points out that, if the research is of non-therapeutic in nature various features of present guardianship statutes may require modifications. The manner based on the guardians are fixed, the extend and scope of their roles and capacities, the rationale on which they rely their decision, the percentage to which involvement of the research participant during the procedure of informed consent to facilitate, expiry of the term of guardianship, and several other features also consisting of an assessment of mental competency.

There are certain matters which need to be done immediately to accommodate these needs like:

1. The issue of confidentiality
2. The manner of accessing the documents,
3. Need for a review of decision made by the person participating in research or his guardian who is appointed as per the prescribed law,
4. Modification in guardianship laws etc

**Types and Phases involved in Medical Research**

There are different types of medical research like, treatment research, prevention research, diagnostic research and quality life research. Treatment research involves treatments by way of experiments, different and modified combinations of medical formula, or new mode of surgical methods or radiation treatment. Prevention research includes for better methods to restrict ailments in individuals who doesn’t had any ailments or preventing an ailment from coming again.

This method involves drugs, preventive medicines, providing vitamins, minerals, or changing the style of living of people. Diagnostic research is carried out to understand better ways or methods for investigating a specific disease or ailment. Quality of life research (or Supportive Care trials) explores different methods to find out the different ways of living with comfort. This is also known as experimentation for support and care to live a better life.

The medical research consisting of human beings as research subjects include: studies of how a human body operates, the nature of chemical processes happening in human body or why and what are the causes of diseases through laboratory examinations or of the response to
a particular procedure in healthy research participants or people with some diseases. It also includes medical experimentation to identify, restrictive or means of treatment in a bigger groups of individuals formulated to show a specific type of consequence to these measures against a group persons of a particular origin.

The research on human beings also aim at conducting experimentation formulated to identify the consequences for persons and society of particular restrictive and treatment methods and studies dealing with health of human beings and behaviour in different types of surroundings and environment.

The foremost phase of the process of invention of a new medicinal product is to find out a potentially drug molecule. Before marketing a particular drug the safety and efficacy may be ascertained. Along with the in vitro studies, almost all biological reactions of the molecule may be classified and identified in animals before starting experimentation with humans. The experiments are initially carried out on human beings before applying any medicines on human subjects. This is essential to identify unknown hazards.

It is not an easy task to identify the real nature of a newly introduced method of treatment. Identifying whether the efficiency of a new medicine compared to the prevailing procedure or method is very important. The matter to be proved is whether the new method may do away with harms presently involve and also whether it can save life better than available medication.

Experimentation involving human beings typically pose serious risks to research subjects, no matter how many animal tests have preceded them. So it is essential to study the ethical concern raised by clinical research and the possibility of exploitation.

Enormous costs, from $100 million to over $500 million, are involved in the developing a single successful new medicine. Medical research is commonly considered as a therapeutic application or health of the corpus related experimental research in human beings that proceed in a well designed protocol.

The Stages of medical research begins with designing of the drug and discovering the drug, proceeding to testing the drug in animal, then starts the testing of drug in some human
beings and further testing is conducted in many number research participants if that stage of research appears and proved to be safe and useful. Before medical research is carried out in the human beings, the safety and effectiveness of the new medicine is normally experimented in animals.

There are many criticisms in using animals in medical research as many scientists believe that the outcome of research with animals may not be used for the benefit of the human beings because of the biological differences. In many cases animal research is supported when there are benefits to health care, no unnecessary sufferings occur and no alternative methods exist.

There are many research studies which give evidences that many animal research study develops into potential therapies for human beings. There are also instances of wastage of animal studies as it is of no use for humans because it is badly carried out and not examined through systematic reviews.

Such type of animal research concludes with the opinion that, the therapeutic importance of animal research calls for urgent notice. Researchers and the society often treat it as axiomatic that research involving animals has initiated the treatment for human ailments.

The evolution of new medicinal combination generally consist of normally twelve years. Five plus years for pre-medical research and six years for medical research. The medical research evaluation stage may need 30 clinical research trials for testing one compound.

Clinical evaluation of a medicinal product goes through various stages, from mode of action of medicines in human beings to investigatory research in specific research participants with a particular disorder. This stage leads to drug testing in a large number participants where the safety of the product and its effects with the available medicinal formula and therapy.

Medical Research is carried out in four stages. The medical research on its each and every stage consist of different objectives and aims and is done to find solutions to different problems.

**Phase I trial**

For evaluating and assure the safety of the experimental drug, the researcher applies it on a
small group of people. The issues which need to be identified are safety, appropriate dosage range, and also to establish the side effects if any. What shall be the dosage of the drug in the subsequent stages is also tested in phase I.

In phase I how a drug is transformed and broken down inside the human body and how it effects in the process of excretion is also studied. Generally those who are fit and healthy are enrolled for the phase I trial. But for testing the drug for diseases like cancer, phase I research subjects may be patients who have already undergone treatments and there is no hope with existing and approved therapies.

Indian guidelines for good clinical practices describes the aims of research in stage I as to ascertain the utmost acceptable dosage which may be administered in human beings, medicinal effect, risk and unfavourable reactions, if any, with their mode and magnitude. The researcher tries to find out the effects of medicines and the methods and mode of their action and reaction in human body.

Phase I research studies are usually performed in fully healthy adult participants. The researcher uses this method in which he makes use of treatment given to the research participants by observing them. The researcher in this stage of medical research tries to investigate on the chemical process happening inside the human body. He tries to evaluate the effect of the procedure on the functioning and operation of the human body.

**Phase II trial**

After the successful completion of the phase I trial, the researcher advances to a phase II trial normally consisting of around 200 research subjects. The main study done in the phase II is to identify the safe use of the medicine and side effects, clear cut description of appropriate doses, and to evaluate whether the medicine is going to have the desired effect and therapeutic value.

It is in this second phase the drug is normally tested in the actual patients. Compared to phase one trial the number of research subjects on whom the study is done is usually less. The therapeutic use effective range of the dosage and safety of the drug is also affirmed.
**Phase III trial**

In phase III trials, the study drug which needs to be experimented is given to a large population. The effectiveness of the drug is confirmed, the side effects are closely evaluated. In this stage the new drug is compared to the accepted and recognized medicines available.

Another task is to accumulate information through which the experimental drug is used safely. People from different localities and background will be enrolled in a phase III trial to test whether their experiences differ. If the medicine is already tested and accepted in other countries, trial is primarily done to confirm its safe application on the patients of a particular nation when it is specified in the monograph of the product for which the claim was made.

**Phase IV trial**

Phase IV experiments are carried out only after the medicine is brought to market. Pharmaceutical products are categorized and trials are carried out on which authorization for marketing will be granted usually in the form of surveillance done in the post-marketing stage, assessment of the medicinal value, different strategies adopted during treatment, measures adopted for safety etc. In Phase IV stage also the same strategy of the ethical and scientific standards may be adopted similar as that of pre-marketing stages.

Thus research on human beings progress in a commonsense manner which has been conventionally differentiated into above mentioned stages. These stages are divided for convenience for a continuously growing process. It begins with a single subject closely observed in the laboratory and proceeding in tens of subjects through hundreds of research participants to thousands prior to that particular combination is agreed as a medicine by national as well as international legal framework and is licensed for prescribing.

In India medical research may be conducted as per ICMR guidelines, provided ethical considerations may not be flouted. When human beings are the research participants there are certain necessary conditions to be taken care of. The aim and objective of such experiments
are for generating awareness and for the welfare of all species in universe.

Medical research may be organized under specific policy that no one becomes simply a procedure for the benefit and welfare of others and that research participant’s dignity, privacy and wellbeing may be protected. The research need to be done under proper transparent professional standard. Appropriate care may be ensured that the research participants are not put at any level of risk than what is permitted taking into account the wellbeing of the research participant.

Medical research consisting of human beings as research participants may be supervised and overseen by systemic evaluation at all levels and stages. Each evaluation need to consider the objective behind the research and the anticipated results, the risk involved in that particular procedure and the benefits to the society. Ethics demands that when a researcher seeks knowledge about safety and efficiency of medicine, which is for a social good, the dignity of the individuals may not be overridden. When a researcher is needs to make a decision on an ethical ground it may be a very hasty process.

He may not see the ethical principles properly defined, rationalized, and logically justified. A close observation of medical research reveals that it has turnout to be more formalized and institutionalized as much effort is taken to make certain that the conduct of medical research is based on the principles of ethics particularly in terms of safeguarding the rights of the participants of research.

**Understanding the roots of human rights violations and some illustrative models**

Taking into account all the different phases and stages of medical research it is evident that it is natural and unpredictable that a best intentioned researcher may go wrong about the efficiency and safety of the procedures involved. Even though all research has a design to guide how to go forward, the failure to achieve expressed value formulations leads directly to moral turpitude and pragmatic failure.

The risk and the consequent harm involved in these stages may be remedied to a great extent by practising and employing ethical and moral guidelines and principles during the stages of
medical research. It is essential that all medical experimentations may be conducted based on a strict principles based on ethical values or standards to infuse trust on the public and to the participants.

The death of several women from very modest backgrounds during the course of a 15-year US-funded medical research which was conducted without giving adequate information to give informed consent has triggered a raging debate about its ethicality as it is evident that many are pitilessly performing crude and cruel experiments and killing lacks of human beings for medical research. Process of exposing human beings to risks in order to collect data introduces the possibility of exploiting subjects for the advancement of medical science and there by benefiting the humanity at large.

History shows several instances of healthy people subjected to various experimentations in order to find out different aspects of ailments and their treatments. We have to identify the root causes that lie behind these events. Ensuring the safety of everyone that comes into contact with health sector is one among the major hurdles of today’s health care sector.

The main aim of this thesis is to bring about major improvements in the quality of medical research by studying from the past. When something goes wrong we should learn from the experience and through that learning, strive to reduce the risk to future research subjects.

The necessity of performing medical research prior to a medicine attains a regulatory permission means that medical research itself is a big market. There was a trial conducted in Hyderabad to identify the efficacy of recombinant streptokinase. Gulhat reports that more than seven people who were administered this drug died. The research was conducted by Shantha Biotechnics without obtaining clearance from the concerned authority as pointed out by Genetic Engineering Approval Committee (GEAC).

When the whole issue of malpractice in the name of medical research came to the limelight the company conducted the research denied the allegation saying that they were given approval to conduct the study by DCGI. Even when all these mishaps occurred no one is bothered about the life of those who died during the research. Gulhat points out that in this
dangerous act nobody is concerned about the life of those who have died or no concern arise about compensating the loved ones of those who died.

No enquiry was conducted to find out the real cause of the death of the research participants. The reasons for the death were certified as death causes other than the use of drug. The life of the human beings where not given any status. Humans where treated worst than animals. Many criticised as animals in many other countries have much protection and rights than human beings in our country.

Under the US Animal Welfare Act any research done with animals before obtaining approval from the Ethics Committee is fined Rs 120,000 (US$ 2,500). These types of unethical practices are possible in India only because of the fact that the rules and regulations on this issue are not stringent or they are not properly implemented. Even when these malpractices come to limelight no action was initiated by the authority.

Woodward opines that, In USA the legal framework for a medical experimentation with human being emerges from principles of Nuremberg Code and Declaration of Helsinki. Protection and interest of the basic rights of research subject need to have predominance over the interest of the medical knowledge and humanity as per the provisions of the Declaration of Helsinki.

The principle relating to reduced risk along with the special procedure and process adopted in the name of informed consent forms the corner stone of the regulations by which US government ensure to safeguard the privileges and welfare of the research subjects.

In medical experimentation increased funding rate as compared to earlier time, use of technologies, introduction of improved clinical tools etc are creating greater demand for human subjects. Access to records of the patients and physiological materials are also increased. Overall there are new measures and steps nationally and internationally to degrade the rights of the research participants to those of scientific knowledge and society.

With the recent controversies surrounding the ethical concerns of medical experimentation with human beings, and advantage of bringing these issues to the notice of parliamentarians,
there arise many concerns revolving the procedure of medical research involving human beings in India.

The matter of concern revolves around ensuring the true nature of acquiring informed consent, and how to evaluate and ascertain the safety of the research subjects, the occurrence of large amount of deaths during the course of medical research, and the issues concerning how to indemnify in cases of any injury or death.

Many researches where conducted in India to find out the status of clinical trial participants which revealed the pathetic conditions of the research participants. Media reports on these issues have brought out very negative impression about the manner and the procedure in which such research is conducted. These concerns along with the real fact that there is a lack of regulatory framework in India has raised many questions on the medical research involving human beings in India.

Even when the legal framework mandates the registration of medical research with the registry for medical research India and the recently mandated requirement of registration of ethics committees (ECs) with the Drugs Controller General of India is not enough to safeguard the research subjects in medical research. The main reason being the lack of governmental audit and accreditation procedures.

The research institutions are not much benefited from implementing these human research protection programme. These programmes may safeguard the claims, and safety and wellbeing of subjects of medical research, along with improving the processes and procedures for the conduct of the trial. What about the lawful rights of the research institutions are also need to be identified.

There were many reports of instances of illegal medical research involving human beings in India. During 1976-88, more than thousand women having different range of cervical dysplasia are included in a medical research for a long term basis to investigate the rates of progression to malignancy. After the completion of the study, 71 women had developed malignancies.

The researchers failed to follow the informed consent principle and other ethical requirements as majority of research participants were uneducated and from lower strata of the society. In
India illegal and barbaric type of medical research have been carried out in New Delhi, West Bengal and Karnataka in 1998. There was no licence obtained for the use of quinacrine under the Drugs & Cosmetics Act, 1945.

A writ petition was filed against the distribution and use of Quinacrine as a means of non-surgical sterilization on women. The import, production, sale and distribution of quinacrine was prohibited based on the provisions of sections 10-A and 26-A of the Drugs and Cosmetic Act, 1940. This mode of sterilization, inserts pellets of quinacrine are into the fundus of the uterus which results in inflammation of the uterus which is followed by the formation of scar tissue which is expected to close the Fallopian tubes and hence result in sterilization.

The effect of this type of sterilization is high pain, body ache, dizziness, painful menstruation, irregular bleedings etc. The chances of failure were also very high. There were reports that this method has caused ectopic pregnancy in the fallopian tube with fatal side effects to both child as well as the mother.

In regional cancer centre, Thiruvananthapuram, kerala, from November 1999 to April 2000 medical research was done on 26 patients having cancer without even conducting any study in animals. Because of hue and cry from the public, media and from the part of the NGOs the authorities were compelled to initiate appropriate steps and proceedings on the incident.

The physicians who conducted the research study were accused of having breached ethics in medical research, opined that the research was conducted with the informed consent of research subjects, hospital ethics panel, and also have informed the government officials about the said research.

The government’s intervention resulted in withholding the research for six months. ICMR also initiated an enquiry into said allegations involved in the medical research. the health ministry in India and the University which sponsored the research also started investigating the allegations that levelled against the doctors that they breached ethics when they conducted the drug testing on Indian patients with oral cancer.

The drug was developed at Johns Hopkins. When all these incidents were happening Johns Hopkins University was already at under black mark because of it’s over use of inhaled hexamethonium in medical research involving human beings for asthma.
In 2003 the Monthly Index of Medical Specialities in India report that, a research study was done on around 400 women who had been attempting to conceive. The study was conducted without their knowledge or consent to take part in medical research conducted in many places in India to test whether a medicine named Letrozole induce ovulation.

The judiciary has in several cases discussed the ethics and morals which a doctor needs to be maintained in his profession. Judiciary commended about the pious nature of the medical professional. The medical science and the professionals engaged under it are engaged in several humanitarian actions.

A physician is approached by the society as the sole hope when an individual is dragged between different types of ailments and good health. There are many cases in which the physicians neglect to duty to take care of the injured person when he needs the care and treatment of a qualified medical professional. Such a conduct from the part of the physician occurs in most cases when he gets the information that the matter is a medico-legal issue.

The court was not reluctant in mentioning that the legal experts and lawyers need to respect the members of medical professional. The court specified that special attention and care need to be taken to see that doctors need not be called to give evidence unnecessary.

The court also opined that members of medical profession may not be harassed by way of adjournments or by any other legal proceedings. Medical professionals may not be dragged away from the people who really need their presence.

Even though this judgment of the apex court relates to medical practice it may be extended to medical research also. This judgment can form as a basis of fixing duties and responsibilities of medical profession. Thus the significance of medical research involving human beings for evaluating the effects of newly developed drugs cannot be placed excessive emphasis in promoting and providing health services.

New and improved medicines, drugs and therapies can produce better quality and lifespan of its users. While it is crucial that the conducting of medical research involving human beings increase, the Government is also trying to preserve the safety of research participants. Measures are also needed for ensuring the standard and level of the research performed in India should rise to international standards.

Taking into account the irregularity and malpractices prevailing in this stream of health service the government of India on November 18, 2011, drafted of the Drugs and Cosmetics (3rd Amendment) rule, 2011, and made it published in the Gazette of India. The strategy was to implement it within 45 days after publication. Along with this, a draft guidelines regarding scheme for compensation was posted for comment.

It is specifically mentioned in these guidelines that research subjects who incur any injury consequent to the participation in medical research are eligible for get it indemnified for impairment or disability. In an extra ordinary manner, the supreme court of India made the union and the state governments parties to PIL, asking them to furnish details of medical research in their jurisdictions.

The Supreme Court of India while hearing a suit which claims many cases of abuse of individuals who got involved in medical research in Madhya Pradesh by an international pharmaceutical company, opined that strict direction may be issued that all these medical researches which affect the life of many individuals must stop forthwith. The court expressed deep concern over the laxity and lethargy shown by the authority on such a very serious matter. The court pointed out the precious nature of each and every human being.

The court also opined that the entire medical research may be stopped unless the ministry of health furnishes accurate and clear information about the issue within a month on issues of concerning and the general manner of conducting medical research with human beings as research subjects. If this is the case it is really disgusting. Human beings are subjected to severe violations of basic human values under the cover of medical experimentation but, the government is still not vigilant on these unprofessional practices.

On questioning the government said that they are taking action but the fact is that simple penalties are imposed on researchers who are responsible and that too without any proper
investigation. When any mishaps results to the research subjects when experimentation is in progress and as being the research participant swift and speedy initiation need to be there from the part of the government in compensating the victims.

The judges expressed the apprehension that even when notice was given to central government when rendering judgment on the PIL, no response was there from the side of the government of India. The court also directed both central and the state government to answer on this issue within six weeks.

Deciding to participate in medical research is not an easy task, no matter where the research takes place or who the researchers are or who is sponsoring the research. Before participating the research participants were given several information about the risk, pros and cons involved in the proposed research.

Common man approaching for treatment may not understand what is being explained about the risk or the benefit. He looks for the cure of his disease with less expenditure. In addition to these severe issues affecting the human dignity and privacy the stark differences among rich and the poor consumers of the health care sector, and concerns pertinent to quick growth of medical research taps the poor and vulnerable section of the society as research subjects. During the resumed hearing of a PIL filed by an NGO Swasthya Adhikar Manch, the court sought an end to illegal medical experimentations of untested drugs by multinational companies.

The NGO has alleged that massive medical research involving human beings which is estimated at Rs8,000 crore is conducted annually by various pharmaceutical firms, using Indian citizens as guinea pigs. The petitioners Swasthya Adhikar Manch (SAM) had argued before the court that a committee of experts of experts may be formed, consisting members of civil society especially, All India Drug Action Network, to examine the present legal provisions concerning clinical trials both in India and abroad and to make recommendations for framing guidelines on the issue.

An application lodged by two Bhopal-based NGOs in the pending petition by Swasthya Adikhar Manch had asserted that leftovers of the carcinogenic poisonous gas leak from Union Carbide factory in Bhopal 30 years ago and being treated at Bhopal Memorial Hospital and Research Centre were being used as 'guinea pigs' for clinical trial of new drugs.
During hearings on purported disregard of laws by pharmaceutical companies in organizing medical research on humans, the court had directed the health ministry not to continue with the medical research of 157 new drugs/formulations till a stricter laws for regulating these research was put in place. Records kept at BMHRC indicates that medical research was conducted on 279 patients of which 215 were gas victims. At least 12 of them died from medication given and many were poor patients who depended on the hospital for free of cost treatment.

The gas tragedy victims on whom these trials have been done were really ill. They were fighting their last battle. The hospital authorities understood that they are not going to survive. Hence, they carried out the trials on them. Because the doctor and the hospital were getting money for every patient enrolled opines social activist Rachna Dhingra.

Even these numbers are difficult to believe because the records kept in the hospital don't seem to be complete. According to the Central Drug Standards Control Organisation, seven drug trials were conducted at the BMHRC but the hospital records show 10 and documents filed by pharmaceutical companies with the US government show 13 trials were conducted. The Drug Controller General of India has; however, know only three of these trials. On a media meeting he said that he cannot say anything unless he gets the details of how the ethical committees gave approval for this.

When the same questions on trials conducted were asked about a year ago, we were told that the trials stopped in 2008. We forwarded that report. But now since you're telling me this, we will definitely investigate this matter, said Secretary, Health Research Dr V M Katoch CNN-IBN had shown in 2010 how drug trials were being conducted in hospitals in Madhya Pradesh. The Supreme Court has now come down heavily on the central and state governments.

In another incident of illegal medical research in Duggmugudem mandal a tribal girl died due to vaccination (human papilloma virus vaccine). The mother of the girl petitioned before the concerned authorities to get the post-mortem results of her daughter available to her. She asserts that before this incident of vaccination her daughter, was in ideal health position.

The death was immediately after taking the HPV vaccine. The vaccine was administered without the consent of her parents at the interest and knowledge of the warden school which
was conducted for the welfare of the tribal’s in which she had studied. She said and condemned that she failed to attain a copy of the post-mortem report even after running after it for a long time. She approached the concerned officials with a request to seek compensation for the death of her daughter, but all were in vain.

AIDWA general secretary Sudha Sundararaman contented that the state is trying to combine the HPV vaccine in the universal immunisation programme. This was done without taking into account the concerns put forward by the expert committee report. The government, which poorly failed to supply anti-rabies and other basic vaccines, has been trying to promote the HPV vaccine without arriving at a conclusive proof over its efficacy at the behest of some multi-national firms she alleged.

Medical research of the HPV vaccine were permitted on vulnerable tribal girls in the name of demonstration project turned to a blatant violation of the guidelines of ICMR. It is essential that the government may indemnify the families of the tribal girls those died due to the aftermath of the vaccine and also to the girls, who developed health complications after administering the vaccine.

There are many supporters to the view that strict punitive measures may be initiated against the erring officials those who are responsible for the illegal medical research. Only if strict actions are initiated the repetition of such cases in future may be avoided. Even if the medical research was under the supervision of the Supreme Court nothing has been done to change the situation in reality. It has been reported that at least 370 deaths resulted during medical research in India since February 2013, but only in 21 cases compensation has been paid.

The amount varied from Rs 4 lakh to Rs 40 lakh. Medical experts are of the opinion that, there is no clarity on the criteria to decide compensation. The data relating to medical research come from the researchers and the research institutions. It is not at all possible to check the credibility and authenticity of the data.

After the direction given by the Supreme Court, the government and drug controller general of India (DCGI), supervise the quality of drugs as well as different stages of research, currently formulated and announced specific guidelines for conducting medical research and
recording and lodging of information pertinent to deaths.

The authority has also formulated a scheme determining monetary damages to those who die during medical research. According to the new law brought in January 2013, an independent expert committee monitors the reported adverse events and makes suggestions to the licensing authority or DCGI, which will finally take a call on the amount of damages.

The Apex Court of India on Jan 14 2015 ordered the union government to answer to the question as to what initiation it took on the report given by the standing committee of the parliament regarding various malpractices on medical research of cervical cancer vaccine involving human beings.

The apex court pointed out that the health of its people is one among the prime responsibility of the government. The government need to take measures to ensure that the health of its people is preserved. The court also opined that it is the duty of the government to take necessary action on the report submitted by the parliamentary committee.

The apex court questioned the government to submit an affidavit explaining who shall be held liable for any adverse effects and death of human beings who are subjected to medical research. The court directed to file affidavit mentioning the procedure of getting informed consent from those who are subjected medical research. The court directed to ascertain the aftermath and the consequence of vaccination.

The court also asked to probe into whose responsibility is to pay compensation. The bench questioned the reason of conducting or selecting that particular state and district for the conduct of cervical cancer vaccine. The apex court also directed the concerned state which sanctioned the research to give information about how many research participants died or injured.

The health expert opines that the biggest drawback for the medical research is the lack of regulatory framework. The expert committees constituted for monitoring registered deaths are in metro cities whereas companies carry out experimentation in remote villages and towns. The research subjects in the rural areas are often unaware about the after effects and inherent risk consequent to medical research.
The DCGI and other authorities claim that there is enough process to protect the interest of the research subject. The industry was confronting a slowdown since 2012 after continuous guidelines from the apex court for safety methods for patients enrolling in medical research. The medical research in India is pegged at over Rs 3,500 crore and is growing at 10-12% yearly.

Undoubtedly medical research is an uncertain activity, in which there is no substitute for learning and training on sick patients. Sometimes mistake may happen, results in injury or even death may occur. The question to be answered is what sort of mistakes is permissible? How often a researcher is allowed to make mistake? How the government can deal this issue? It is essential to formulate specific regulatory framework that governs medical research involving human beings.

**Objectives of the Study**

1. To spotlight the historical viewpoint on the status of human beings involved in medical research.

2. To analyze how much the conduct of medical experimentation on human beings is performed in consistent with the norms of human rights.

3. To make a comparative study of the guidelines, principles and legislations to preserve rights of research participants.

4. To examine the present legal framework relating to medical research involving human beings in India.

5. To critically assess the Bill and to make suggestions for suitable changes to accommodate the protection of the vulnerable and marginalized sector in the Indian society when medical research involves people from backward and marginalized sector.

**Hypotheses**
1. Medical research involving human beings is mandatory to test the efficacy of a drug.

2. Medical Research which is non therapeutic in nature and affects the basic human rights of the research participants.

3. The laws safeguarding rights of the human research participants in India is conceptually flawed resulting in extreme incidence of human rights violations of the research subject.

4. The adoption of the western doctrine of informed consent as such to the Indian socio cultural and economic backward society resulted in the failure of the legal system.

5. The inadequacy of a specific rule for safeguarding the human research subjects and the public cry for protection of their rights may reduce the conduct of medical research in India and adversely affect the pharmaceutical companies in India.

Research Questions

1. Does cultural and social background has an important role in deciding on health issues?

2. How do the International Human Rights and humanitarian concerns address the issue of protecting the rights of the human research subjects?

3. Is the present legal framework is an efficient tool in providing protection to the human research subjects?

4. Do the rights guaranteed to the victims by the Bill lead to restorative justice?

5. Do the judicial interference and interpretations facilitate in promoting the rights of the research participants in a medical research involving humans?

Methodology
Research Methodology is a combination of Doctrinal, and Analytical Research Methods. Doctrinal Research includes review of the ethical theories and legal principles dealing with medical research involving human beings. The present legal framework dealing with this issue is analysed in detail and the loopholes are identified.

The analytical study explores the need for a specific strategy for employing the principle of informed consent which suits the vulnerable Indian society. The implications of fixing criminal liability on researcher/research institutions are approached in a critical manner.

The materials relevant for the study are accumulated basically from primary and secondary sources. National and international guidelines and statutes are widely relied on. Along with these documents authoritative books, case laws, articles of peer reviewed journals, newspaper reports on medical research involving human beings are also looked into.

**Scope and Limitation of the Study**

The study is an examination of adequacy of the legal framework for medical research involving human beings in protecting basic human rights of the marginalized and vulnerable section of the Indian society. To understand the problems and issues of the medical research involving human beings, the ethical and moral responsibilities of a physician is analysed in detail.

The historical background, development of and acknowledging the rights of the research subjects, procedure for employing the doctrine of informed consent are explored in an international perspective. To understand the present Indian legal framework of medical research involving human beings, a survey of accessible laws are made.

The merits and demerits of international and national guidelines and principles are explored in the Indian cultural, social and economic background. The study explores the impact of health care guidelines and legislations and how far the right to access to justice of human research participants is protected. An extensive study is done to identify the loopholes prevalent in the existing legal framework to deal with the issue and suggest appropriate recommendations in par with Indian socio, economic and cultural values to control and defeat the same.
The methodology is confined to doctrinal mainly because of non availability of accurate information when attempted for an empirical method. Getting information about heavily invested medical research by multinational companies became impossible or every time inaccurate and non reliable data was received. Conducting interviews of stake holders involved was seem to be just a repetition as interviews usually appears in medical and medico legal journals.

The multifaceted dilemma of the victims including children, women, insane is analyzed from the view point of the access to justice .Concisely, taking into consideration the inherent limitations involved in this study, an effort is made to analyze the historical context, ethical and moral principles, the present prevailing legal framework to encounter the issues of medical research involving human beings in India. An enquiry into the provisions of the proposed bill is made to analyze to what extent it serve the purpose of Justice.

i Vincent v Union of India , 1987 AIR 990, 1987 SCR (2) 468

ii Industry Report, Healthcare: India, The Economist Intelligence Unit, July 2014


iv (32 CFR 219.102.f). (Lim,1990)


viii Art 17(1)(ii) ECHR.

ix Art 17(2)(ii) ECHR.

x Article 19 The Declaration of Helsinki ( October 2000)


Ethical Guidelines for Biomedical Research on Human Participants 2006

http://www.jli.edu.in/blog/clinical-trial-phases/

Ganapati Mudur, Indian study of women with cervical lesions called unethical, BMJ 1997;314:1065.

Rakesh Bhatnagar, End illegal drug trials: Supreme court, Published: Friday, Jan 4, 2013, 7:00 IST, | Place: New Delhi | Agency: DNA.