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CHAPTER 5

THE LEGAL FRAME WORK OF MEDICAL RESEARCH IN INDIA

India is emerging as a favourable destination for medical research involving human beings. Legal frame works are safe devices to ensure that the general excellence of standard and righteousness of data accumulated in medical research is preserved and also to make certain that the individuality, privacy, dignity and welfare of research subjects are safeguarded.

In India there are three types of regulatory frame works and procedures which may be categorized as Law, regulations and guidelines. In the category of Law we have the legislation specifically for the Drugs and Cosmetics passed in 1940 and axillaries rules passed in the year 1945 as a mandatory conduct to be followed and enforced by a controlling authority. The implementations of these laws are specified in schedule Y given along with Drugs and Cosmetic Act which is issued by the CDSCO, administered by DCGI, Delhi. The guidelines are not mandatorily pursued and are not invariably accepted.

The drugs & cosmetics Act, 1940 includes the authority for managing, safeguarding and ensuring standard, protection and also to test the ability to produce a desired or intended result of drugs and medical research outcome. The essential formalities, procedures and legal frame work have been formulated under 1945 rules for Drugs and Cosmetics.

The rules, for carrying out medical research with human beings in India are prescribed under Rule-122DA, 122DAA, 122DAB, 122DAC, 122DD, 122E and Schedule Y. Before carrying out a medical research involving human being in India, authorization and consent from the DCGI need to be obtained. Consent from ethics committee where the study is decided on is also necessary. It is also mandatory that the study need to be registered on the ICMR website.

Latest amendments in Gazette Notifications relating to medical research involving human beings for testing the efficacy of a newly identified drug or medical research Amendment vide Gazette Notification G.S.R. 53(E) dated 30-01-2013 mentions the rules and schemes for evaluating the reports of Serious Adverse Events related to medical research and schemes for
remittance of damages in case of research allied damage or death as per authorized and mentioned time limit.

This rule specifies that in the happening of some injury to the participant of the research, free of cost medical services may be provided till it is required. In the extreme cases of death as a consequence of enrolling in the medical research the legal hairs are entitled for financial compensation as per order of DCGI.

Nearly all established pharmaceutical companies of the world have medical research operations in India. A large number of Indian and global clinical research organizations are conducting human trial services for the pharmaceutical companies around the world. According to the National Institute of Health USA, there are 925 clinical studies are currently happening in India.

The time to recruit the research subject in India is much less when compared to other western countries. Minimal time to recruit results in substantial cut in the overall cost of the highly expensive and time consuming clinical research. India is currently the second most popular destinations for companies that want to undertake such trials. Each nation has its own drug regulatory authority to deal with drug related issues.

**Drawbacks to carry out medical research with human beings in India**

According to pharmaceutical companies, there are several difficulties to conduct research in India. DCGI lacks the expertise as the technical staffs are not medically qualified doctors. Along with these difficulties, even though, India has many medically qualified persons, only very few are trained in good clinical practice, in addition to these, hospitals pathology laboratories with enough infrastructure and other facilities to conduct research are very few.

In such a pathetic situation, illegal and unethical trials have attracted the coverage of media. Sponsors of the research cannot claim the sole ownership of the data which they accumulated through research, because research reports are in the public domain.
The manufactures of generic drugs can make use of the information to attain approval from the regulatory authorities for their own versions of drug. Even though only with a prior approval from health ministry and family welfare duly taken from the director general of health services any medical research may be initiated in India, with the increasing number of medical research, the general concern that the Indian population is exploited at the hands of big pharmaceutical companies as guinea pigs has also increased\textsuperscript{vii}. The guidelines for recruiting human beings for medical research are not strictly followed in India. In this background in 2000, ICMR has formulated an ethical guideline to be followed in cases of medical research on human subjects.

The aim behind the drafting the guidelines is to eradicate the unethical and substandard practices in the name of medical research. ICMR is a research organization. It does not have the power to take any punitive actions. The DCGI is the regulatory authority to conduct medical research. Schedule Y of the Drugs and Cosmetics Act applies to research of new medicines. Approval must be received from DCGI for other research as well of medicine which have received permission in other nations but need to be marketed in India.

Under the Drugs and Cosmetics Act, all trials in India may follow the ICMR guidelines of 2000. The Medical Council of India (MCI) Act, amended in 2002, states that all research in India carried out by physicians has to follow the ICMR guidelines. So there is indirect power to enforce our guidelines.

The Drugs Controller doesn’t have any responsibility for stem cell research. ICMR drafted the stem cell guidelines at the request of the Drug Controller. The ICMR has a mechanism of review for its own institutions. Supervising private labs has become a matter of concern. Every doctor is governed by the MCI Act. Any doctor doing wrong in a trial or in practice can be prosecuted. The hospital can be closed. The MCI has the power to take punitive measures.

The Drugs Controller has authority over any clinical trial for which DCGI’s permission has been sought and functions under the Drugs and Cosmetics Act. But if someone conducts medical research with an approved drug without getting permission from the Drug Controller and something goes wrong, then the Drug Controller will not come to know.
The Drug Controller has the power to initiate and institute an inquiry on hearing or a report relating to the alleged event. Getting the information of the medical experimentation by the pharmaceutical companies is a very difficult task.

When analyzing the law suits filed by subjects of medical research due to research related injuries, one may find that many legal theories are being asserted like, negligence, recklessness, not obtained proper informed consent, medical misbehaviours, product liability, causing of emotional hardship, deprivation of human dignity, violation of body autonomy, infringement of constitutional rights, action against international obligations, breach of the rights of dignity, privacy, commission of battery, fraud, conspiracy, research misconduct, breach of contract etc. Analyzing the theoretical basis for fixing the liability of the researcher may lead to a better understanding of the regulatory measures.

**Contractual liability of the researcher**

The principle of informed consent transforms the essence of the doctor-patient fiduciary relationship to a contractual one to promote individual autonomy and freedom of choice by making the researcher to give the research subject all knowledge that make him an equal bargaining partner. The connection between a person doing the research and his research subject is a contractual one.

A contract between parties who are competent. It gives rise to contractual obligations. Indian Majority Act stipulates that the parties are considered to enter into a valid contract if the parties are above 18 years of age and if they are of sound mind and also when they are not disqualified by any relevant law of the jurisdiction to which they are subject to.

Moreover, the law of contract mentions that the consent of any person obtained by any vitiating elements may render the agreement invalid. According to the Indian Good clinical Practices a Contract means, an agreement between two or more persons. It may be written, dated and signed document. Delegation or distribution of duties, arrangement of financial matters also need to be mentioned. The “Protocol of the research study” may form the basis of “Contract between the research institution and the research subject”\(^{\text{viii}}\).

According to US FDA informed consent procedure does not create an obligation between researchers and subjects. US research subjects are not safeguarded by the law of consumer protection. The general form of informed consent in U.S tells an individual going
through medical research that, by being signatory to this form one cannot waive their legal rights, but the form doesn’t gives any information of those rights.

The clause in the consent form relating to the subjects injured due to any medical experimentation conducted inside U.S state that, if any injury results as being part of the research then treatment will be provided. All the expenditure connected with this therapy will be given to the insurance company of the research participant.

Other expenditures which do not covered by the insurance company need to be met by the research subject. Because of insurance deductibles, co-payments, and lifetime benefit limits, injuries in medical research leads to a very expensive affair to most injured research participants. The US patients without health insurance usually may not try to participate in medical experimentation.

Informed consent form also mentions that the sponsors of the research will pay for injuries relating to research. One condition which is stipulated is only those injuries which are the direct result of medication will have the insurance cover. It is also essential that the research participants need to follow all the instructions of the research team.

**Criminal Liability of the Researcher**

To touch someone or to administer to them a noxious substance, without their consent is a criminal offence. Any treatment or procedure carried out on an individual in the absence of consent of the research subject, could amount to a criminal offence, unless it is done in good faith for the benefit of a person. However in certain circumstances the consent of the victim for the touching may provide a defence.

There is no offence if a researcher conducts any medical experimentation with the informed consent of the research subject. Thus a person may not be guilty of any offence if he causes injury to another, if such injury is caused during the course of properly approved medical research. It very much rely on the clauses and terms of the contract concerning with harm and damages.

The research may be properly approved otherwise may be held criminally liable if causes harm to the patient, even if the patient has consented. A person should not be guilty of
an offence if he causes injury to another, of whatever degree, if such injury is caused during the course of properly approved medical research approved by Local Research Ethics Committee and with the consent of the participants.

If death occurs, the researcher may be prosecuted by the police and charged under criminal proceedings for causing the death of the research participant by a rash and negligent action not amounting to culpable homicide under section 304-A, IPC, if such death was a result of gross negligence, gross carelessness, gross ignorance or undue interference from the part of the researcher. In cases of serious injury, the doctor may be charged under Sections 336, 337 or 338, I.P.C. These provisions are invoked when the degree of negligence is so grave that mere compensation may not result in justice.

To attach criminal liability under Section 304A IPC the degree of negligence need to be higher than what is need to be proved for fixing civil liability. To impose civil liability what is need to be proved is that the researcher did not exercise reasonable care, but criminal liability may be fixed only if the researcher’s negligence was gross amounting to recklessness.

The apex court of India in Jacob Mathew v. State of Punjab has given some guidelines to safeguard the rights of the physicians from frivolous complaints of medical negligence. Even though the degree of liability for researcher in medical research involving human beings need to be higher as medical research in most cases are non therapeutic in nature the guidelines given by the Supreme Court may be made applicable to the researchers also.

**Researchers liability in tort**

Fixing tortuous liability on medical professionals is too much burden on the health care sector. Presently, the judicial interpretations throughout the world follows the principle that if informed consent is not obtained properly or material facts relating to the research is not disclosed to the research subject it end ups as a liability in negligence.

The word negligence covers both act and omission. Omission is abstaining from doing something that a reasonable man ought to have done in particular circumstances. Negligence is actionable under both civil and criminal laws. If negligence is the main component of the
case, the liability of negligence need to be showed by the prosecution as culpable or gross and not negligent simply grounded upon a mistaken judgment.

To fix a liability based on a claim of negligence requires four essential features: firstly the defendant’s duty to confirm to a specific standard of care, secondly, non-observance of that duty, thirdly, a seminal connection between failure of the defendant to confirm to the duty and injury inflicted to the plaintiff and fourthly the injury need to be compensated.

A type of legal fault, not necessarily involving a mental state is negligence. A researcher is negligent when he owes a duty to take care to the research subject and there is a breach of this standard of care. The standard is determined with reference to medical opinion and the courts decide whether this standard has been met or not. The person undergoing the medical research has to demonstrate that it was the breach in the duty that caused the damage and the damage was not too remote.

A patient approaching a health care professional may not be ignored. Even though a doctor has the right and freedom to choose those patients he may serve, he may respond to any sort of assistance which the public expect from him in case of emergency. If already engaged with a case, the doctor may not disengage the person approaching for treatment, or he may not depart from the case without informing the patient, his relatives or the legal guardian or friends sufficiently long in advance about the withdrawal.

This will help them to approach another medical attendant. The court in this case opined that no provisionally or fully registered medical practitioner may intentionally commit an act of negligence that may not provide his patient or patients any necessary medical care.

Negligence is not conforming to professional criteria to be adopted while conducting a medical procedure. A researcher owes a research subject a duty to take care based on the delict of negligence. He could be sued for damages in case of any breach to that duty. Every health care professional, doctor, nurse, hospital authority may exercise reasonable care in all circumstances. In some circumstances law envisages a duty.

When the claim is based on negligence, the research subject must prove not only the breach of duty to inform, but also that had the duty, not been broken, he may not have chosen to
participate in the medical research. The delictual liability arises when there is a duty.

The duty arises from the relationship between the researcher and the subject. When the researcher doesn’t confirm to the professional standard of care required from a reasonable and professional researcher, it leads to breach of duty. The breach of duty by the researcher if results in any damage to the research subject, the theory of causation under delict is also fulfilled. Then naturally it results in damages.

Once the patient is given information about the nature of the procedure involved and if he gives consent to the proposed medical research, that consent is considered as real. The cause of the action based on a claim of failure to confirm to the standard of care which leads to risks and implications is negligence. A person who projects himself as ready to conduct medical research possess certain duties to the research subject.

From the breach of these duties emergence a right to fix civil liability on the researcher. A civil liability based on a claim of negligence to the research participant. Where an unexpected outcome results from a situation under the control of the researcher and the experts opines that such incident would not have occurred if taken required care and caution, it is an action of negligence.

Such cases falls under the doctrine of Res Ipsa Loquitor, but to prove the conduct of a researcher as negligent under this doctrine is not an easy task because uncertainty is a prominent feature of medical research. Even though there are definite protocol for every research study involving human beings risk and uncertainty is hidden in every face of a medical research involving human beings.

A failure to act like a common man in situations which demand such behaviour mandated by law is negligence. When consent is defective, the proper cause of action may be either battery or negligence; the difference between the two is on the outcome for both plaintiff and defendant.

Jerome Hall distinguishes two extremes in the relevant legally significant mental states—negligence and intention. A person conducting the research will owe a participant a duty of care in the tort of negligence. A suit for damages may be filed against him in case he breaches
that duty.

The distinctive essence of negligence is inadvertence, precisely non purposeveneness. Medical research morally requires compensation on a no-fault basis even where there is proper consent on the part of the research subject.

A researcher may practice to the best of his ability and within the limits of his expertise. The level of disclosure of material facts in medical research is very high. A common man researcher standard is required when telling the research subject or disclosing strictly whether or not a study is done for their personal advantage.

The research subject may be properly informed that their participation in the medical research may be with free consent and without any compulsion dedicated for the advancement of scientific knowledge. In 1965 a Canadian judgment says that the obligation of disclosure in medical research is as good as and not better than, the obligation of ordinary physician/surgeon to patient, with no privileges for any type of therapy or waiver.

Thus the standard of a professional is a matter of medical judgment. Only if a researcher has acted in this manner, he falls within the standard of medical judgment. Moreover, the doctor has a obligation to reveal all material facts to the person approaching him for the treatment. Similar is the duty of a researcher to the research subject.

Getting informed consent from a research participant from a patient in America is often considered from the point of view of a prudent knowledgeable patient. It is commonly described as the prudent patient test. There the research subject’s right to maintain self determination is respected. This may lead to a so-called objective test of disclosure wherein the researcher will keep in mind the wellbeing of the research participant and provide all necessary material and valid facts and data which is considered as essential and required to be given.

A good researcher need to step into the shoes of the research subject and decide what is good for him along with his motive to find out the effectiveness of a new drug.

The purpose is to enable the patient to exercise her right to choose whether or not to
have the particular operation or treatment to which she is asked to give her consent. Every individual has an absolute right to choose what may and may not be done with his body. Any one interfering with that right even if with consent, must take the care expected of a reasonable researcher. In all circumstances the researcher has an obligation towards the research participant to provide adequate information relevant to make the informed choice.

Thus in medical profession negligence is understood as not confirming with a reasonable standard of competent medical men. So in order to impose duty of care of the researcher, the harm must be foreseeable. The Connection between the researcher and the research subject must be sufficiently proximate. It need to be fair, just and reasonable. Only if all these are fulfilled, on the occurrence of the breach of duty, liability may be imposed.

The policy considerations and balance of interest are different in the treatment and research. The duty is imposed on the researcher to disclose all the risk which may reasonably be anticipated not just the usual and most frequent risk. But the problem is that of enforceability of standards as they are the minimum international standards of conduct governing bio-medical research on human subjects. If we adopt and extent the bolam’s test to medical research similarly as that of the medical treatment, establishing that the individual researcher has fallen below the standard of a reasonable researcher is not an easy task.

Taking into account the fact that, a research program can only potentially harm the volunteer’s health, the legal standard of disclosure may be higher than for medical treatment. So separate criteria may prove effective for research and treatment in fixing liability. Great caution is needed in its application. A doctor who engages in medical experiments with human beings may have his conduct more severely scrutinized than one who acts for the purpose of treatment. In treatment there is no pertinent need of alarming the patient about the procedures adopted, but in research it is a necessity.

**Constitutional Provisions guarantying the rights of the research subjects**

Men are born and remain free and equal in rights. Social distinction may be based only on common utility. The aim of all political associations is to preserve the natural and imprescriptible rights of man. These rights are protecting the liberty of every individual, ensuring the security and right to resist oppression.
Every citizen has the rights guaranteed in our constitution against any type of oppression. The survival and the progress of any society depend on the good health of its people. The health cannot be compromised for the sake of advancement of the medical science or for manufacturing of new drugs.

The conduct of medical research involving human beings need to take into account the rights protected in the constitution. Man has certain basic, essential and inalienable rights and it is the duty of the state to recognise these rights. But mere recognition of these rights is not enough. They must be made applicable. It is being argued that enforcement of human rights is a major significance to modern jurisprudence.

Judicial interpretation to right to life makes it clear that life means to live with dignity. One may be given the right to protect his body autonomy, Right to decide what may be done on and with his body. When we consider the wordings of Article 21 and the interpretation given by the judiciary a research participant’s right to life may be restricted in accordance with fair, just and reasonable procedure established by law.

The pertinent thing to be followed is that the procedure cannot be arbitrary, unfair and unreasonable. Article 14 strikes at arbitrariness. If a research participant is recruited without following necessary norms and principles it is arbitrary, unreasonable and unfair. The theory of reasonableness which logically as well as philosophically, is an pertinent feature of equality or non-arbitrariness. It pervades Article 14 like a brooding omnipresence and the procedure contemplated by Article 21. It tries to answer the test of reasonableness in order to be in conformity with Article 14. It tries to guarantee against arbitrariness in state action.

Indian Judiciary has several times interpreted the constitutional provisions to protect the health rights of the citizens. Health care and protection are not directly incorporated giving it the nature of fundamental right in the Indian Constitution. DPSP imposes duty on states to adopt necessary measures for the betterment of health care rights of the individuals. The legal structure and the responsibilities of the state agencies to take care of people’s health and ensure physical and mental well-being is the yardstick of a person’s right to health in a welfare state.

Health, as a sector, does not appear as such in many places in Indian constitution. There are only indirect references to health of the people and the role of the state in its protection. India
has many national provisions and health care legislations along with policies adopted by the governments as a safeguard and protection of health care rights.

The Indian Judiciary through its various judgments interpreted the constitutional provisions to guarantee and ensure that ideals put forward in the constitution either as fundamental rights, directive principles or international principles enshrined in various conventions and treaties envisages that those can be legally implemented for the welfare of society at large. Even though all these legislations and progressive and timely interpretations by the judiciary are there, India is failing to achieve full justice and protection to the research participants when testing the efficacy and safety of new drugs.

It is essential to examine the constitutional provisions for the protection of health care to understand the role of the state in its protection and enforcement. In preamble under the term Social Justice, the question of accessing health Care facilities, equality and the principle of justice are envisaged. Article 38 of Indian Constitution fixes liability on the government to ensure a social order for the betterment and welfare of the individuals who are coming in contact with the health care sector.

Article 41 stipulates and impose duty on government for assistance, for those who are confronting with any type of disease and ailments. Article 42 enables to safeguard the health of infant and mother by making provisions for maternity benefit. In India DPSP under the Article 47 mentions a primary duty of the state to make provisions to improve the health conditions of the general public and for making provision to secure justice and wellbeing.

The rights of the children against unethical and profit motivated pharmaceutical companies conducting medical research need to be protected. Children form one among the vulnerable group of the society. The constitution provides provisions for the protection of children from abuse and exploitation. The state has the power to make special provisions for the welfare of children under Article 15(3).

Article 39(e) and (f) of the constitution also directs the state to promote welfare of the children. Under these provisions the state is mandated to direct its policies to secure the childhood and youth against exploitation. Protection to equal opportunities along with
circumstances to grow in a healthy atmosphere and in situations of freedom and personal dignity whereby guarantying the right of childhood and adolescence against any type of exploitation, moral and material abandonment is the constitutional right of a child against unethical medical experimentation.

Article 243G says there may be proper legislations empowering the panchayats with essential power and authority with regard to issues mentioned in the eleventh Schedule. The particulars mentioned in the eleventh schedule have direct relevance to concerns relating to health, women and child development, imposing responsibilities on the panchayaths.

It is within the duty of the panchayaths to take care of women and child care and development, family welfare, Primary health centers and dispensaries, welfare of the society, Public health, safeguarding the interest of weaker sections of society, Vital statistics including registration of deaths etc.

The village panchayats has the power and authority to function as units of self-government by the 73rd Amendment Act of 1992 and part IX of the constitution was inserted titled “The Panchayats” giving significant implications for the health sector. Thus right from the national level to the grassroots level the state is liable to improve and protect the public health. When the people from the vulnerable sections of the society is involved in the medical research, it may be better monitored in the grass root level using the powers given to the panchayats.

The apex court interpreted the terms of Art.21 to include right to health under its terms since health is pertinent for improving the standard of life making it meaningful and accordance with personal dignity. The state has a duty to safeguard and preserve the human life which is of paramount importance.

Article 21 of the Constitution fixes the duty on the State to protect life. The terms of the article as interpreted by this Court several times brings more strength in claiming the protection of life against the state. A physician working in a government hospital is liable to fulfil this duty of the state. A professional obligation is cast upon every physician whether at a Government hospital or otherwise to provide his services with due expertise for safeguarding the life of a person approaching him.
A similar obligation is there when a researcher makes a protocol to perform a research with humans. The research participant may be informed about all the pros and cons and the harm and advantages involved in the said research. It may be evident to the researcher that the research participant understood the factors explained to him. Disposing of the Writ Petition, in the case of paramanantha karta’s case the court held that, Article 21 casts the duty on the State to protect and preserve life.

There can be no second view that protection of human life is of great importance. That is because of the fact that once life is gone, the status quo ante cannot be restored as resurrection is beyond the capacity of man. The patient whatever is his status before the society, whether he is an innocent person or a criminal liable to punishment under the laws of the society, it is the duty of those who are in charge of the health of the community to preserve life so that the innocent may be safeguarded and those who are guilty may be punished.

Laws laid down in the society do not contemplate death by negligence to tantamount to legal punishment. Every physician whatever be the sector in which he is associated with, whether at a Government run hospital or a private sector has the professional duty to provide his services with due quality experience for preserving life. There can be no law or any state action which may delay the actions of the members of medical profession.

Treating a person in medical need is the superior duty cast upon a person in medical profession. Any statutory or procedural law which curtails this duty cannot be sustained. The Supreme Court instructed to give enough publicity to this judgment through media and also through high court, District court and lower judiciary. The court emphasized that as a welfare state it is the responsibility of the state to give medical services to all.

**Drugs and Cosmetic Act 1945, Schedule Y.**

The specifications of schedule Y of Drugs and Cosmetics Rules form the basis of medical research’s legal frame work. Schedule Y applies to medical research to test the efficacy of new drugs, but permission must be sought from the DCGI for other trials as well, that is, for
those drugs which have received approval in other countries, but have to be marketed in India. Earlier, all foreign drugs need to be retested at one phase that is below the highest phase of testing done abroad.

In January 2005, the government of India introduced a rule which allows foreign pharmaceuticals and other interested parties to conduct medical research for finding out and testing the efficacy of a newly introduced medicine in India. This new rule supersedes a directive of India’s Drugs and Cosmetics Rules that required a “phase-lay” between India and the rest of the world.

According to the old rule, if a phase 3 study had been completed elsewhere, only a phase 2 study was permitted in India. The old rule was designed to protect Indians from being used as guinea pigs in the testing of unproved drugs of foreign origin. The change was made in response to the demands from multinational drug companies and private organizations that conduct clinical research for a relaxation of the rules of drug trials.

By virtue of the amendment effected to Schedule Y in 2005, India can become part of global trials, but even then phase 1 has to be repeated for safety. Schedule Y specifies the mode and method to carry out medical research involving human beings in India.

The way in which the medical research may be conducted in India is related with numerous elements such as, is the medicine is discovered in India or anywhere else, Is the medicine is accepted for marketing in some other nations or whether subjected to research in any other nations etc. Before requesting for granting permission to conduct medical research, it is mandatory to specify that the medicine is not subject to any restriction or withdrawn by the authority in any other country.

The Rules stipulates that medical research may be initiated by a Sponsor after receiving the required approval of DCGI. It is also necessary to obtain a test license for the import or production of a new medicine. The Sponsor has a duty to submit reports regarding the method of conducting and results of the medical research to the DCGI, even when not intend to market that particular medicine. Medical research is carried out by the researchers, who administer the medicine to the volunteers after receiving their informed consent and collecting the required data.
Dr. Vasantha Muthuswamy opines that, the fear is that India is portrayed as a universal hub for medical research. Whether ethics committees of each research institution are strong enough? Whether the members are well qualified to understand each and every stages of medical research and the implications of post trial benefits? Will the local Institutional Ethics Committee is properly equipped to ask the right questions?

Empowering the local Institutional Ethics Committee is the only way to control the research at the moment. Presently there is nobody to monitor the Medical Research. India doesn’t have a monitoring mechanism. The DCGI gives approval but there is no way to know how they are doing the trial. So there is an urgent need for clinical trial monitors.

The guidelines relating to the medical research is enforced through the office of DCGI under the DSCO. DCGI permits a new drug application after identifying that a medicine is safe to use and also efficient for its particular use. Genetic Engineering Approval Committee (GEAC) is the office to check the efficacy and safety of any medicinal product.

Food Safety and Standards Authority of India (FSSA) makes rules and regulations regarding food supplements, etc. A registry for medical research involving human beings has been set up by the ICMR’s National Institute of Medical Statistics (NIMS) and who ever who desires to carry out a medical research in the India has to produce required documents for the research.

It is also necessary to furnish status of the ethics committee approval and the certificate stating regulatory clearance by the DCGI.

Good Clinical Practices is formulated for assuring good practices while conducting medical research in India. It is a guideline to ensure uniform quality of medical research throughout the territory of India. A committee of professionally qualified standard group set up by Central Drugs Standard Control Organisation (CDSCO) after discussing with medical experts has designed this GCP guideline for when obtaining data regarding drugs. It encompasses design, carrying out, termination, audit, analysis, reporting and documentation of the studies involving human.

The main principle enshrined in GCP is that, the priorities of science and society may never take control over matters concerning the welfare of the research participant. These guidelines have been evolved with consideration of WHO, ICH, USFDA and European GCP guidelines.
as well as the ethical guidelines for biomedical research on human beings issued by ICMR.

Indian GCP points out that, Research participants who incur any physical damage because of their involvement in medical research are eligible for damages or other supports to indemnify them equitably for any temporary or permanent impairment or disability subject to confirmation from IEC. If death results their dependents are entitled to material compensation. As it is only a guideline they may not be enforced strictly as that of any legislation.

**Compensating Human Research Participants**

Even after a long history of debates, there is not yet a commonly accepted conclusion about to what extent human beings who encounter with any sort of injury due to their participation in medical research are eligible to claim monitory benefits that may indemnify equitably for the lose they suffered.

Fixing liability on the health care professional was not a usual practice earlier. Medical professionals were considered as those people who act on behalf of gods for alleviating the sufferings of those who confront with various ailments. Health care profession as a whole were considered as a noble profession for the welfare of the human race. With the advent of time and the development of health care sector as contributing towards the economy, the nature of the relationship of the providers of health services and the consumer of the health service has gone through several transitions.

When we trace the major developments in the world on this account, in UK a doctor may not be held responsible for negligence if his actions are based on an accepted practice of medical professionals. This practice later on approved by the court in the judgment of Bolam’s Case.

In U.S, the liability of the doctor depends on whether or not complying with the procedural formalities of the theory of Informed Consent. If the physician doesn’t provide adequate information about the proposed treatment he will be held liable under the principle of negligence. The sanctity of fiduciary nature given to the parties of medical service has diminished to a great extent with the commercialization of medical field. In India the
enforcement of liability of medical professionals are delt through various actions which may be categorized as liable for damages, criminal actions, disciplinary, recommendatory etc.

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The crucial factor which determines the tortuous liability of the health care professional is whether he has confirmed to his duty of care. To fix liability on health care professional the evidence need to be adduced as he has not taken standard care and was lacking competency and prudent skill which resulted in some evil consequences that may not have happened if taken enough duty of care. In the claim of negligence, damage is a pertinent factor of cause of action.

The material factor which needs to be proved is the negligent act of the researcher which is the real fact resulted in damage to the research subject. If this fact cannot be established the researcher cannot be held liable under tortious liability principle.

Even if it is successfully proved that the action of the researcher was negligent and it resulted in unwanted consequences the researcher may not be eligible for compensation unless he demonstrates a connection between the breach occurred and the loss he suffered. Once the researcher has gone through the test formulated under the Bolam’s case, he needs to confront with the principle of Causation.

It is essential to prove that the researcher’s act or omission is the crucial factor leading to injury or death happened to the research participant. If this cannot be established there can be no liability under tort and the action fails.
Essential features of the theory of causation which makes it a complete one to fix liability in negligence:

1. The injury or death might not have resulted but for the researchers negligence.

2. The researcher’s negligence substantially contributed to the risk of injury.

3. If the claim of the research participants is of negligent non-disclosure, had the research participant been properly and sufficiently informed he might not have accepted to be a part of the research.

The ‘but for’ test:

The research subject need to prove that the damage which has occurred might not have resulted if the researcher’s conduct was not a reason leading to it. The injury or death might not have happened, but for the conduct of the researcher it happened.

Causation and non-disclosure of the material fact:

The research subject need to prove in case of negligence that if he had been informed about the inherent risk he would not have accepted to be a part of the research.

A review of strategies adopted by the government in cases of medical research related injury in India demonstrates that almost half of all surveyed investigators were not aware of their responsibilities and the procedures for the management of research-related injury.

The scheme for compensation need to identify what is damage relating to the medical research. A damage or death resulting from adverse effect of investigational products, non-compliance of the protocol which has been approved by the authorities, misconduct, malpractice, negligence, recklessness on the part of the researcher or sponsor, lack of therapeutic effect of the investigational product as specified, using placebos in a placebo-controlled research or trial, harmful effect due to associated medication not considering standard care, entailed as part of approved protocol, damage to a child in the womb as a
result of the enrolling the parent in a research or trial, injury due to any clinical trial procedure involved in the research study or trial.

All these can be categorized as natural consequences of the negligent or reckless conduct of the researcher incurring him to pay compensation to the victim. Even when enrolled or volunteered for medical experimentation the research participants may not be the direct beneficiary.

Especially in cases of experimentations of cancer and all the possibility of risk is very high. The research participants may die during the conduct of medical experimentation. It is very difficult to prove the exact nature and the reason for death in such cases. They were suffering already. It is difficult to prove whether because of medical research their ailments have increased or aggravated.

The case becomes more complex when the question of compensation arises. There are many instances in which a treatment failed even with accepted and properly licensed drug. The application of placebos may not prove good and show therapeutic benefits to all individuals. This results in another form of discrimination.

Indemnifying the victims in medical research is a real complex concern which mandates very careful evaluation and consideration. In the case of medical research also it is essential to consider the grade pointed out by CIOMS and WHO in cases of causality of adverse events like:

1. Not related
2. Unlikely
3. Possibly related
4. Probably related
5. Definitely related

Another guideline widely used is that of the Association of the British Pharmaceutical Industry on compensation for medical research related injuries, which recommends that
subjects suffering from research-related injuries be compensated on a “no fault” basis, with seven basic principles.

1. First, even without any of legal obligation, the research institution or the pharmaceutical company may pay damages to research participants if they suffer bodily injury even in the cases of death.

2. Secondly, damages may be paid when, the cause of injury may probably resulted due to the action of the medicinal product under investigation or because any intervention or procedure during and as part of medical research. It is essential to prove that the injury might not have occurred if not been enrolled for the medical research.

3. Thirdly, children in utero are treated as volunteers.

4. Fourthly, damages may be given only for more serious and irreparable injury, including exacerbation of a prevailing situation, and not for pain suffered for a short time or comfortless or less serious or curable ailments.

5. Fifthly, damages may also need to include the unintentional outcome of any act and when administering an adverse event.

6. Sixthly, the issue that the adverse reaction was foreseeable or predictable, and that informed consent was obtained, does not limit the research subject from getting damages.

7. Seventh, to avoid doubt the burden to prove defect in a product or negligence in the procedure adopted rests with the research subject. These guidelines for phase II and III trials clearly state that they don’t apply to phase I research in volunteers who are not patients or to licensed drugs or to independent trials initiated by doctors who are responsible for the health and welfare of their patients.

Drugs and cosmetic rules makes provisions for compensating the victims of medical research if death or injury results. According to the rules the amount of compensation to be paid is
decided by the ethics committee who have sanctioned the research. There are many criticism against this as the chances for a fair decision on the amount of compensation may be very minimal and also because the decision of the ethics committee was also final.

Majority of people enrolled for medical research suffers from one or some other type of ailments. It needs very efficient and professional medical expertise to decide the root cause of injury or death. There were lots of criticisms that the ethics committee has no expertise to decide the reason for the death or injury to decide the quantum of compensation.

There were also suggestions that the mode and method of compensation adopted in the motor vehicles Act 1988 may be made applicable to medical research related injury or death also. Another suggestion was to follow the injury compensation model followed by US in the vaccination related injury. It involves a no fault method which gives damages to all eligible persons who suffered injury during vaccination. The damage is paid from the public exchequer.

To make a framework of an acceptable formula on compensation for medical research related injury or death, there are several factors which need to be taken into account. Age of the research participant, the factor of risk involved in the research, percentage of the probability of the risk, economic background of the research participant, medical condition of the research participant at the time of the death, probability of survival of the research subject, the family background and the number of dependents of the person suffered injury or death.

Negligence, Recklessness, inadvertence etc of the researcher during the course of medical research which resulted in evil consequence. How long the research participant suffer the particular ailment under investigation is also may be considered as a factor to decide the amount of compensation.

The percentage of probability of the medicine to result an evil consequences or chances of any procedure done as part of the medical research to cause any injury or death of the research participant may also form a criteria to decide the amount of compensation for the research subject who suffer injury or death.
The concern of the supreme court on not adequately compensating the human medical research participants who suffered serious damage or death has resulted in constituting a committee to look into the issues of compensation. The ministry of health and family welfare is given the charge relating to this matter. The committee gave structure to a formula to ascertain the amount to be indemnified in medical research involving human beings.

The information furnished by the central government of India in the S.C when asked for an accurate data on death consequent to medical research with human beings was shocking. The number of research participants died comes around 3000. The reports show that the victims were not compensated.

The scheme provided under the compensation for clinical trials under the 2013 bill may be summarized as:

- No medical records without approval and permission.
- Care and medical assistance and damages for damage due to medical research.
- Deferment of medical research data requirements by the central licensing authority.
- Ethics committee need to be duly registered.
- Constitution of ethics committee.
- Functions and duties of ethics committee.
- Punishment for carrying out the medical research in human beings relating to cosmetics without approval.
- Punishment for violating the procedures of permission.
- Punishment for repeating the same offence relating to medical research involving human beings.
- Punishment for not indemnifying the victims.
- Punishment for violating any provisions of the chapter of the bill relating to medical research involving human beings.
- Confiscation of stock
- Taking cognizance of offence.
- Authority of union government to frame rules.

In addition to these provisions, for rendering justice to medical research participants the drug controller general of India formulated three independent committee of
The expert committee may examine the cause of serious adverse events of death and give its suggestions to the Licensing Authority within 30 days of getting the report from the concerned Ethics Committee.

The DCGI has the power to decide the amount of compensation as deemed essential within three months of getting the report on serious adverse events of death or injury. The research institution /sponsorer of the research may be made liable to pay compensation within thirty days of receipt of the order of DCG(I).

For ascertaining the amount of compensation payable in case of medical research related damage or death, several factors came for discussion before the expert committee.

- Age of the research subject
- Risk factor of death
- Income of the research participants
- Expectancy of survival of the research participant
- Dependency of the research participant
- The nature of medication taken by the research participant
- Negligence from the part of the researcher during the course of medical research.
- Nature, type and duration the ailment of the research participant while enrolling for the medical research.

Among these factors some were finalized by the expert committee like, age of the research participant, the factor of risk depending on the seriousness and intensity of the disease, the factor that the research participant was under medication at the time of joining the medical research etc.

The expert committee came to the consensus that for considering the age of the research participant to calculate the amount of damages the factors prescribed in the Workmen Compensation Act may be taken in the case of medical research compensation cases. The committee has graded the risk factor in five grades like,
• Terminally ill patients
• Patients with high risk
• Patients with moderate chances of resulting in adverse events.
• Patients with lesser amount of risk
• Patients who are physically fit and are healthy or lesser subject of no risk.

To identify a base amount the committee adopted the base amount as 8 lakhs considering the minimum wages on date which may increase or decrease with the changes in minimum wage from time to time.

Thus after much discussion with the expert committees, the most appropriate method to calculate compensation was formulated by DCGI. It includes factors like age of the research participant, the factor of risk involved in medical research and the base amount to calculate the quantum of compensation.

Service Tax Exemption for Medical Research

When reflecting on the ability to develop and create a trade or profession, which may considerably gain foreign exchange for the economy and at the same time benefit the healthcare industry in India, the Central Government had given a better standing to medical research industry on the understanding that it will be excluded from Service tax.

In actuality emphasizing the significance of the industry for India, the Finance Minister in his budget speech in 2007 pointed out that to bring up India as a desirable destination for medical research it is essential to make provisions to exempt medical research of new drugs from Service tax.

The exemption survived till 10 July 2014 and was accessible to services of technical testing or examination of recently developed drugs, together with vaccines and herbal remedies, on human research subjects by a clinical research organization (CRO) endorsed to carry on medical research by the Drug Controller General of India (DCGI).
There were many complications with regard to earlier exemption from service tax. Firstly, no CRO was commonly authorized by the DCGI but what was accepted was a medical research involving human beings and the permission could be given in the name of the sponsor or a site etc. secondly, the exemption did not wrap up the current drugs, thirdly, it did not acknowledge expressly medical devices thus resulting in confusions and cases.

Some of stakeholders in the medical research string like sites and principal investigators (PIs) were already being examined in pockets by Service tax authorities particularly after July 2012 when all services, except a few specified services, were brought under the scope of Service tax.

While health service in general are absolved under a specific exemption, administrative experts may furnish an argument that medical research related care and treatment services were not given to the patient but to the sponsor and thus not shielded under health benefits.

As a result of these restraints in the current exemption from Service tax, the industry was thinking of approaching the government to widen the scope of exemption particularly to cover other players in the medical research process besides the CRO and open the scope of products brought under exemption. A few representations were actually made before the previous Government as well as the new Government. There was total abruptness relating to these provisions after the introduction of 2014 Budget.

Not only that the plea of the industry was not appraised by the Finance ministry, amazingly even the prevailing exemption was withdrawn. Finance Minister precisely mentioned in his budget speech that “For the betterment of the attempt to widen the tax base, certain exemptions are taken away, including those relating to technical testing of newly introduced drugs on human participants.” The Finance Minister has abolished the theories which his forerunners has upheld seven years back to encourage pharmaceutical companies conducting medical research.

The industry will now be burdened with the Service tax resulting the services dearer by 12.36 per cent. Even the export related advantages to the services could be confronted as services of any kind of testing are usually presumed to be where tests are conducted. Therefore, the foreign earnings regardless of, the industry may be asked to shell out Service tax. In fact
taking away of the exemption has sent a wrong message to the global community on the government’s undertaking to upheld medical research pursuits in India and disrupted investments hitherto accomplished.

**National Ethical Principles on Medical Research**

In India, there are general ethical guidelines applicable to medical research consisting of human research subjects. Along with these general guidelines there are specific guidelines relating to drugs, privacy/ data protection, human biological materials, genetic, embryos, stem cells, and cloning.

To understand the ethical requirement relating to medical research on human subjects it is essential to review the standards adopted for these categories also as they often overlaps. These non-binding instruments are issued by those organizations which does a national oversight role for human subject research.

In 2000 an ethical guideline has been formulated for social science research by the National Committee for Ethics in Social Science Research in Health (NCESSRH). ICMR has issued The Ethical Guidelines for Biomedical Research on Human Participants (2006), ICMR has also issued The Ethical Guidelines for Biomedical Research on Human Subjects: Statement of Specific Principles for Clinical Evaluation of Drugs/Devices/Diagnostics/ Vaccines/Herbal Remedies (2006).


**The Ethical Guidelines for Social Science Research (2000).**
All technological and scientific pursuits, inclusive of those conducted by the social scientists, involving of human beings as research subject have an effect on human beings or on the society and the environment at large. Taking into account all these factors it is essential that scientists/researchers look into the ethical issues and the aftermath of their scientific actions and act accordingly. The guidelines gives an ethical background based on moral or normative principles that are relevant for ethical conduct of medical research in India.

The ethical principles are based on the moral context of the relevant situation. A principle-based structure guide the researchers in formulating their moral principles to argue to choose the most relevant and ethical step in the given context. When considered from this sense, the guidelines are not rules of administration, but they are acceptable standards giving a choice in all actions in a concrete situation. The core of comprehension and applying ethics and guidelines is the thought to safeguard and protect the human rights of the research subjects.

**Guidelines for Stem Cell Research and Therapy.**

The law makers around the world are troubling with various ethical questions relating to stem cell research. The mushrooming health care providing centers claiming stem cell treatment for many diseases has compelled the government to draft certain guidelines to regulate the conduct of the persons engaged in stem cell research and therapy. Indian Council of Medical Research (ICMR) and Department of Biotechnology (DBT), Government of India, have formulated certain guidelines to regulate Stem Cell Research and Therapy (SCRT) in India.

It is specifically mentioned that the stem cell Research can be conducted when it is essentially a research with potential health benefits. The Researcher may give due respect to dignity of an individual, basic human rights and freedoms that are very much fundamental to everyone. Body autonomy of every individual may be respected when consent is obtained.

Consent may always be an informed one. Privacy and confidentiality may be maintained in harmony with the cultural sensitivity and environment. There may be an equitable distribution of burden and benefits. The research may do good considering the
health concerns of persons and society. It may aim at minimization of risk and maximization of benefit.

The guidelines propose a double mode of monitoring mechanism. One at the National level other at the institutional level. In the National level there will be the National Apex Committee for stem cell Research and Therapy (NAC-SCRT) and in the Institutional level there will be Institutional Committee for Stem cell Research and Therapy (IC-SCRT).

It has been made mandatory to register with the NAC – SCRT through IC – SCRT in order to carry out medical research with human stem cells. Depending on the nature of research studies using human stem cells viz., permissive and restrictive approval may be obtained from IC –SCRT or NAC – SCRT. Guideline specifies that new stem cell lines may be created only when it is necessary and also with prior approval of IC – SCRT / NAC – SCRT).

Existing stem cell lines, whether imported or created in India may be registered with both committees. In order to import stem cell line from other Indian Lab permission may be obtained from IC – SCRT. Before importing, the investigator may ensure that the cell line has been established in accordance with existing guidelines of the country.

New clinical trials with any stem cells may have prior approval from Institutional Committee and from DCGI (Drug Controller General of India) and may be registered with the National Apex Committee. In case of trials with International Collaboration, prior approval may be obtained from National Apex Committee, funding agency and also from the Health Ministry’s Screening Committee.

Thus even though Institutional Committee can approve for conducting clinical trials; it is mandatory to report to the National Committee. For conducting new clinical trials with stem cells, the approval of Drug Controller General of India is proposed, since stem cells in effect play the role of drugs. In order to solve the Intellectual Property Rights which may arise in future, a distinction is made between nationally and multi nationally sponsored clinical trials.

The guidelines recognizes three types of stem cells based on their origin, viz, Human embryonic stem cells, derived from the balstocysts, Human embryonic germ cells, taken from primordial germ cells of the foetus, Human somatic stem cells, which are taken from fetul or
adult tissues or organs, including umbilical cord blood or placenta. Blastocysts can be taken either from surplus embryos from IVF clinics or derived specifically for research using IVF, or derived by techniques like SCNT etc.

Commendable factor of these guidelines is that it’s categorization of Research on stem cells viz., permissible, restricted and prohibited. The categorization is made based on the source of stem cells and the nature of experiments. In vitro studies on already established embryonic stem cells or adult somatic stem cells to understand processes of development and differentiation are kept in permissive category.

Establishing Embryonic stem cell lines from spare embryos, provided spare embryos are obtained in an ethically acceptable manner is also kept in the permissive category. As far as in vivo research is concerned, studies in adult animals do not raise any ethical dilemmas, hence it also is permissible.

Regarding the restrictive category, Embryos specifically made for the purpose of stem cell research, by way of in vitro fertilization is strictly restricted. It is restricted to require specific scientific justification and proof of technical competence of the investigator. Another restrictive category is that stem cells being transferred at the blastocyst stage and likely to contribute to germ cells. The reason for restricting such research is, the resultant animals are prohibited to breed. Such a research study needs strict approval of the National Apex Committee.

Reproductive cloning is put in the prohibition category. Similarly, any in vitro culture or manipulation of human embryo beyond 14 days after fertilization, or formation of neural tube, implantation of any embryo after in vitro manipulation into human uterus via germ line gene therapy strictly prohibited.

Separate provision has been made concerning the Research done with the Umbilical Cord Blood Stem cells and Foetal Stem Cells or placenta. Both are categorized as permissible. Cord Blood Banks are considered similar to other blood banks. It is mandatory to register other Cord blood stem cell banks with the DCGI.

The guidelines stipulate certain points that may be considered while collecting umbilical cord blood. It includes protection and safety of mother and child, consent may be informed consent, correct information to the parents regarding the risks and benefits involved
etc. Regarding research using foetal stem cells or placenta, it is stipulated in the guide lines that, termination of pregnancy on consideration is not permissible.

Separate consent may be obtained for abortion and for donating the foetal material for medical research. The doctor terminating the pregnancy is not allowed to use the foetal material for any research purpose. The women have no right to mention the use of foetal material for a specific person or in a particular way. Confidentiality may be maintained regarding the identity of the donor and the recipient.

Permission for taking a New embryonic stem cell line may be granted by the National Apex Committee and the Institutional Committee only when there is no other way to achieve the proposed goal, no existing stem cell line will serve the purpose, research is conducted with the purpose of increasing information on embryo development and reasons of pregnancy and child birth related defects, research study may result in finding out abnormalities in embryos before implantation, the study may use infertility treatment and also when research term have expertise in such area of study. Thus, before giving permission for taking a new embryonic stem cell line either from spare embryos or embryos generated for that need may take into account all these aspects.

Double mechanism is provided for implementation and monitoring of the Guidelines. One through Institutional Committees and the other is that of National Stem Cell Research and Therapy Committee. The duty to decide whether the research falls into restrictive, permissive or prohibited category is vested upon the Institutional SCRT Committee. National Apex Committee on SCRT is also having a duty to lay down policies if need arises.

Thus medical research consisting human beings as research participants may be carried out while taking into account the ethical principles enshrined in the latest revised Declaration of Helsinki. The researcher needs to acknowledge and respect the concept of justice. He need to give due consideration and weightage to respect each and every individual enrolled in the medical research.

The researcher needs to show beneficence to research subject so that his actions may maximize benefits and minimize harms and wrongs. The researcher also has the obligation to do no harm to the research participants. These laws and guidelines are measures to ensure a greater protection for research participants. Indian GCP also points out certain ethical principles that may be followed while conducting medical research.
Good Clinical Practices are standard criteria based on certain quality which is ethical and scientifically acceptable for conducting medical research. Compliance with these ethical standards assures safety and protection of the research subject. GCP or Good Clinical Practice refers to an international quality standard provided by the ICH for the purpose of regulating clinical trials that involve human research participants. GCP criteria offer guarantee as to the effect and safety of compounds developed in medical research, protection of basic human rights, and also define the responsibilities of the medical researchers, clinical trial sponsors and clinical research associates.

**Principles of Essentiality**

Through the principle of essentiality, the employing of human beings in medical research is contemplated as absolutely crucial after considering all available possibilities. The decision that the research is essential has been arrived based on different factors like, presently available knowledge in the proposed area of research, recommended as necessary by a professionally responsible body after considering all factors material to make a decision as to whether that particular research is needed or not.

The proposed research need to benefit all members of the human race and may also benefit the ecology and aim at the well being of the world. There is a need to accept and recognize cultural sensitivity to ensure the principle of essentiality in medical research process while undertaking research among populations having varied customs, beliefs and practices. A uniform approach may not be suitable for obtaining informed consent from them. There may not be any disturbance to the cultural ethics and morals because of the research study.

**Principles of voluntary participation, eliciting consent in an informed manner and consensus of the community.**

The research subjects may be informed the full value of the proposed study. The risk
and the impact of the study on the research subject also need to be informed to the research participants. The research subject may also be informed that he retains the right to withdraw from the medical experimentation at any stage.

**Principles of non-exploitation**

It is from this principle that the concept that the research subjects are remunerated for participating in medical experimentation. Whatever be the social and economic condition of the research subject, they may be informed about all risk arising out of the research.

**Maintaining privacy and ensuring confidentiality**

These principles are employed to see that the identity and data received from the human research subjects are being kept confidential. The information about identity of said research participants, that may disclose their identity, need not be disclosed without effective scientific and legal reasoning.

Disclosing that confidential information is considered as justified in cases where it is absolutely essential for any therapeutic interventions. There is a condition which needs to be satisfied even when it is a case of therapeutic necessity. A written consent need to be obtained from the research participant or from the legal guardian. It may be ensured that the said research participant may not incur any type of hardship or difficulty as a result of the disclosure of the confidential information.

**Minimizing risk and ensuring adequate safeguards**

These principles forms the basis of safeguarding and maintaining safety at all stages of medical research. The researcher is bound to take measures to see that all research subjects are exposed to very minimal risk. Several strategies are adopted to protect the research subject from any adverse effects of the medical research.
Maintaining competency and a professional standard

Medical research is always performed by professionally qualified experts. The researcher needs to act with total integrity and without partiality. This principle stipulates that the researcher may be fully educated about the importance of complying with ethical considerations.

Making the researcher/institutions accountable and maintaining transparency in the research proceedings.

The underlying idea behind this principle is that the medical research may be conducted in a just, equitable, sincere, unbiased and crystalline manner, after complete revelation is made by people concerned with the research. Matters like any conflict of interest, maintaining privacy, preserving confidentiality, protecting the rights of the researcher as well as the research subject, maintaining complete data, publishing of research reports etc. emergence from these principles.

Maximizing the public welfare and maximum distribution of justice

The medical research and the consequent use of the experiment may aim at the welfare and benefit of human kind. The vulnerable and the marginalized section of the society must benefit from the results of the study. Distribution of justice need to be maintained in all stages of medical research, right from the stage of recruiting the research subject till the publication of research reports and also for making the research study beneficial and for the betterment of the humanity at large.

Fixing responsibility on all those who are connected to the medical research.

There may be an obligation on all individuals related to research to make sure that all the process needed to be fulfilled. All the institutional requirements are to be made in respect of experimentation. The subsequent use or applications are duly made with good faith and in a bonafide and transparent manner. It is essential to adopt all required measures to guarantee
that reports of research, materials connected with the experimentation and all information concerning the research are duly safeguarded and archived.

**A Principle based on the evaluation of the research done and making it known to the public.**

This principle forms the reason for the evaluation of medical research and the bringing the response of evaluation into the public domain. The research result are usually published in scientific publications. The law of the particular jurisdiction governs the issues relating to the rights of the researcher and others connected with the research.

**A theory based on a responsibility which imposes a total duty on the researcher**

The ethics mandates that those who conduct the research need to be professionally and morally accountable. It argue for due abidance of all the ethical doctrines relating which rationalize medical research. The moral accountability forms the basis of all ethical principles. All those impliedly or expressly, directly or indirectly related with medical research need to be abide the moral and ethical principles.

**Principles of compliance**

It deals with the common and constructive obligation on all individuals, organizing, connected or attached with medical experimentation requiring the involvement of a human being to make certain the principles embodied in these guidelines, norms and rules particularly mentioned for medical research are to be abide with. There is a duty to ensure that the rights especially of the vulnerable and the marginalized are not infringed. The autonomy of the research subject whatever be the cultural and economic background of the research subject.

For the smooth functioning of medical research, the authorities and the stakeholders need to be more proactive and supportive in protecting the interest of the pharmaceutical sector. There need to be a fair chance of growth of opportunities in the competitive market which is decreasing now a day due to negative media reports on medical research taking place in India.
The DCGI's objection to support the rightful claims of the pharmaceutical companies and bring exact facts to world is becoming a big credibility concerns for medical research industry. This factor is forcing many MNC's to turn its back on India and give business to more understanding and reliable government like, china, Bangladesh and Tailand.

There is a need to put correct facts into place. Streamlining the work of the government for medical research sector, by formulating a strategy that may provide proper dissemination of data on any injury and deaths caused as a result of actual adverse drug reactions (ADRs) by the DCGI's office. This will ensure that the industry is not wrongfully indicted for deaths of any research subjects.

THE DRUGS AND COSMETICS (AMENDMENT) BILL, 2013

The Drugs and Cosmetics (Amendment) Bill, 2013 was announced in the Rajya Sabha on 2013 Aug 29. The proposed Bill is a comprehensive legislation which amends the Drugs and Cosmetics Act, 1940 and modified the name of the Act to the Drugs, Cosmetics and Medical Devices Act, 1940.

The Bill has separate chapters on medical research. It put forwards certain changes in the legal framework of the, manufacture of medicines to ensure safety, efficacy, quality and conduct of medical research. Medical research is defined in relation to drugs, cosmetics, medical, and involves their systematic study with an aim for ascertain their welfare, productiveness, performance or fortitude. To carry out medical research one need to register with the Central Drug Authority (CDA) an over reaching body and get approval from an Ethics Committee registered with it.

The main objective of the Bill is to form a 19-member overarching authority to form the drugs and cosmetics sector under the leadership of Secretary, Health and Family Welfare. The Bill creates provisions for subsequent treatment if needed and damages in case of any harm or death of a person during participation in a medical research. The Central Government shall establish a CDA to subsume the existing Central Drugs Standards Control Organisation. The CDA will be composed of representatives from the Ministries of Health and Family Welfare, Law, Commerce and Industry, Science and Technology, Chemicals and Fertilisers, DCGI, Indian Council of Medical Research, Directorate General of Health Services.
There will be also other experts nominated by the central government, including those from state licensing authorities. The CDA shall among others, specify guidelines, construction and other essential features for the successful working of the union and state licensing authorities. It has the power to examine, wave or call off any licence or approval given by them. It also has the authority to take decision on disputes between two or more state licensing authorities relating to the wordings of the Act and laws and regulations made under it.

**Milestones in the development of The Drugs and Cosmetics (Amendment) Bill, 2013**

Several expert committees have made recommendations for the suitable administration of the medical research consisting of human beings as research subject. One of them, the Mashelkar Committee, The gist of the important recommendations made by the Mashelkar Committee are as under: defective drug control framework at the state and union level, There is a need to strengthen the State Drug Control Organizations with additional manpower, infrastructure, technical capability and financial resources, the issue of non uniformity of enforcement at the State level is a serious matter and needs to be addressed immediately.

The grant of manufacturing licenses should be given by Central Drug Administration (CDA) instead of the present system of grant of such licenses by the State Drug Control Authorities, there is a need to streamline and expedite the procedure and process of approval of applications for new drugs and clinical trials including the need to institutionalize Good Clinical Practices (GCP) where some of the important recommendations.

Based on the suggestions of the Mashelkar Committee, the Government had brought two Bills in Parliament, namely, the Drugs & Cosmetics (Amendment) Bill, 2005 and the Drugs & Cosmetics (Amendment) Bill, 2007. The 2005 Bill was devoted to the problem of spurious and adulterated drugs and enhancing the penalties in the Act therefore. It has already been enacted as the Drugs & Cosmetics (Amendment) Act, 2008.

The Drugs & Cosmetics (Amendment) Bill, 2007 was introduced in the Rajya Sabha on 21st August, 2007. It introduced provisions for regulating medical research in the country. The 2007 Bill was referred by the Rajya Sabha to the Parliamentary Standing Committee on the 23rd August, 2007 for examination and report.
The Committee submitted its observations / recommendations in its 30th Report on the Bill on the 21st October, 2008. There were many developments requiring lots of amendments arising out of the recommendations of the Parliamentary Committee and the comments of the State / UT Governments. The Ministry of Law & Justice (Legislative Department), therefore, suggested withdrawal of the 2007 Bill and introduction of a new Bill in its place.

Almost all the recommendations of the Parliamentary Standing Committee on the 2007 Bill have been accepted and incorporated in the new Bill. In accordance with the Government’s decision, the 2007 Bill has been withdrawn and the new Bill, namely, the Drugs & Cosmetics (Amendment) Bill, 2013 has been introduced in its place on 29.8.2013 in the Rajya Sabha.

The Drugs & Cosmetics (Amendment) Bill, 2013 contains more comprehensive provisions than the 2007 Bill. The new / amended definition of clinical trials is included in the new Bill. Separate Chapter containing regulatory provisions for clinical trials, including penal provisions is one of the important recommendations made in the Bill.

The role of the Ethics Committee under the Bill

All over the world, it is the Ethics Committee that has to look into all these ethical requirements before carrying out medical research involving human beings to identify the effectiveness and how far a newly introduced drug may protect the human beings from a particular ailment.

The constitution of the ethics committee needs to be taken care of. The provisions relating to the ethics committee is mentioned in sections 4T to 4W of the Bill. It is mandatory that the ethics committee should be registered. The Ethics Committee, formulated with the purpose of giving permission to conduct a medical research and other connected issues, may be registered with the Central Licensing Authority based on the procedure mentioned therein.

The ethics committee has been given a fixed time period. The registration given by the Ethics Committee is valid only up to the time span of five years and shall be revived as per the manner mentioned. The committee may involve both medical and legal experts. The Committee consist of seven experts consisting of professionals from medical field, experts with law background, social scientist and also one member from community.
The committee may also consist of a chairperson, and a member-convenor. The Committee may review the medical research periodically. A review on the basis of the progress reports of the study, monitoring reports, reports of internal audits or on the basis of visit to the study premises in the manner prescribed. The committee also has the authority to cancel its permission to a medical research for the grounds which need to be documented.

Whenever there is a medical research involving human beings for testing of any new medicine, it is the ethics committee need to be made accountable as the members of the ethics committee are the people responsible to ensure the good ethical practices when medical research involving human beings are being conducted. No one may conduct medical research on human beings without getting permission of committee formed as per section 4T of the proposed Bill.

The power to ensure the rights, welfare and protection to research subject is given to the Ethics Committee for examining the efficacy of a new medicine. Section reads as follows: 4P. (1) Central Licensing Authority is entrusted with the power to grand permission to conduct medical research to identify a new medicine or a medical device or cosmetic investigation on any drug in human beings. Under clause 2 ethics committee constituted under 4T need to approve the conduct of medical research. Registration of medical research with central Drug Authority is made mandatory under clause 3. To conduct studies on approved drugs no permission is required.

Provisions under the Bill for Injury and Death during medical experimentation.

In the course of medical research if any injury or death results to the research subject, the question as to the cause of the injury and the factors affected to result in such a consequences etc may be decided by the DCGI or the authority entrusted for that purposes.

The scheme of Compensation under the Bill

In respect of Compensation for medical research involving human beings if results in Injury
or Death, the Bill had devised a unique formula for compensation based on several parameters one of which was linking the compensation to the minimum wages in case of an unskilled worker and also with health status of the patient. If death or injury happens due to the involvement in medical experimentation the sponsor of the research or the research institution shall provide him, or legal representative, such amount of monetary damages as may be prescribed by the DCGI or concerned authority, in the prescribed manner xx.

**Penal provisions under the Bill**

The penal provisions are an additional safeguard other than suspension of license by drug regulator in respect of the clinical trials violations in case of deliberate violation resulting in death. The current criminal law is not enough to deal with the malpractices affecting the human rights.

Punitive actions itself is essential and mandatory to deal with this issue. Even though many cases reported with severe malpractices under the cover of medical experimentation, the number of persons subjected to punishment is really less. Only with a legal framework bearing punitive actions the violators may be identified properly and punished.

**The Role of Central Licensing Authority**

A person may carry out medical research for examining the safety of a new medicine or any study in human research subjects only with the approval of Central Licensing Authority in a procedure duly authorized xxx. Medical research shall be conducted only after registering it with the Central Drugs Authority in the prescribed procedure xxii. The authority need to be empowered with those powers to discover, prevent and to initiate and subject erring professionals to the proper sanctioning authority.

**Conclusion**

The DCGI being the authority to issue permission for conducting medical research, certain powers are given to them. There are certain provisions to impose stringent punitive actions for its infringement that consist of imprisonment of up to 10 years and fine of Rs 30 lakh is
also included in the proposed Bill. The proposed bill also gives wide responsibilities to the sponsor of the medical research or clinical trial for testing the efficacy of a newly invented drug on human beings.

The cost incurred for managing medical expenses and monetary damages is the sole responsibility of the sponsor. Wide responsibilities are imposed on the sponsor of the study as they get more advantages from the monetary benefits of the proposed medical research.

The sponsor needs to make an assurance in the form of an undertaking when giving application to carry out medical research that compensation will be provided for medical research or trial related injury or death. The non-fulfilment of this assurance may result in cancelling of the research or trial and the sponsor may be stopped from conducting any trials later.

India was exclaiming for a new encompassing authority to accomplish the difficulty and hardship of the pharmaceutical industry conducting medical research consisting human beings as research participants. Testing the drugs in human beings is the only method to establish the quality, safety and effectiveness of the medicine. It is expected that the proposed Bill will strengthen the drug regulatory system in India with explicit provisions for regulating them.

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i Permission to conduct clinical trial or medical research.

ii Definition of clinical trials.

iii Compensation for injury or death caused due to research.

iv Conditions of clinical trial inspection and permission.

v Registration of ethics committee.

vi Definition of new drugs.

vii Pillscribe, India’s booming clinical trials industry, 462 drug study deaths in first 6 months of 2010 says health mini- http://tinyurl.com/2awowo, viewed on 20/12/2014.

viii Indian Good Clinical Practices.
The Ethical Guidelines for Social Science Research (2000).

Ibid.

4T (2), Ibid.

4U (1), Ibid.

4U (2), Ibid.

4V (3), Ibid.

4V (4), Ibid.

Section 4p(2) of the Bill

Section 4V(2) of the Bill

Section 4 P of the bill

section 4q of the bill

section 4 r (2) of the bill

Section 4p(1) of the Bill

Section 4p(3) of the Bill