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CHAPTER 6

CONCLUSIONS AND SUGGESTIONS

Introduction

The benefits derived from medical experimentations resulted in saving many lives and also for improving the quality of life and also to prevent, detect and to eliminate many diseases. Even if it cannot be prevented there are many ways and methods through which they can be managed much efficiently through new and improved methods of medical processes and therapies. Still many remain to be learned and many things to enhance the standard of health care and human life.

As a nation which protect and safeguards the rights of the citizens what India, need to take care of is to take appropriate measures to identify the actual problems involved in medical research and make proper regulations for the conduct of medical research.

India need to make such regulations which allows the pharmaceutical companies to invest money in India and at the same time ensures the safety of the human beings involved in medical experimentation.

To facilitate the growth and smooth functioning of medical research in India that is both productive and meaningful, the law makers may concentrate on formulating a legal framework which respects the ethical principles and moral obligations of bioethics.

It seems pathetic on the whole legal system to assume, that ethical regulations and codes may effectively protect the research subjects from the malpractices of researches working under national and multinational pharmaceutical companies.

Ethics derives power and strength only when it gets the backing of Law. The ethical principle becomes powerful and enforceable only with the support of Law. The ethical discussions surrounding medicine and in medical research cannot be limited among medical
professionals, but society at large has the right to a dialogue.

Without a means of enforcing or holding accountable all those stakeholders involved in and charged with their respective responsibilities when conducting medical research with humans, philosophical inquiry concerning the rights of human research participants and interests of science becomes a mere academic pursuit.

The researchers, the sponsors of the research, the stakeholders involved in the whole process of medical research together play very crucial and critical role in assuring and implementing safety measures to ensure safe and high standard in the clinical research studies. There should be proper networking and co-ordination between various stakeholders involved in a medical research for safeguarding the human rights of the research participants. Practicing good clinical practices alone does not ensure good research.

A good medical research should be planned and taken up by a researcher who have up to date knowledge about the rules and regulations and also may have the consciousness to abide ethical principles, maintaining proper records, and also in publishing research reports. The researchers must abide appropriate and mandatory guidelines before medical research are allowed to be conducted.

In most cases the committees constituted to evaluate the research proposals are just formal committees. All the data need to be entered properly and need to be certified by the officials participating in the committees. The regulatory framework stipulated in the proposed bill specifies that any research planned in the country needs clearance and authorization.

The definition of the term research subject need to be very clear as not to give any chance for interpretation which leads to ambiguity. The term human research participant may be defined as, an individual on whom a testing is carried out to verify the efficiency and efficacy of a new drug or to compare the efficiency of a new medicine with a prevailing one.

The rights of the participants of the research may mean the rights of the human research participants of medical research which are recognized under various national and international laws and regulations for conducting medical research involving human beings. The rights of the human research participants also emerge from precedents and judicial pronouncements of various jurisdictions which has legal validity. Even the obiter-dicta of the
judgments have persuasive effects.

Medical research has a crucial part in the development of human race because health of individuals is the basis of all developments in the world. Without health the human resources is of no use. Improved and advanced ways to preserve health is possible only through medical research. Tremendous changes in the life style of the new generations resulted in several diseases.

Only through constant and continuous research for new and improved drug and therapies this scenario can be taken care of. Medical research contributes to alleviating different ailments for which there was no treatment earlier. With the commercialization of the health care sector, medical research also has tremendously contributed for the economy of the nation. The share of the pharmaceutical companies in the economy of the present day world is very high.

The basis of medical research is human beings. In medical research the evaluation of the newly developed formulae of drug first goes through various testing and experimentation on non-human beings .That being the common factor and the mandatory requirement of all medical research the accuracy, efficacy and the appropriate dosage of a drug can be correctly determined only by testing it in human beings.

Thus as an essential component of medical research, the human research participants are very much eligible for all the rights associated with their capacities. Only when their rights are protected the medical research may be performed fairly for the advancement of medical science for benefiting the humanity.

Being a human being the research participants are entitled to all basic human rights in all phases of medical research which need to include their right to be informed about all the procedures involved in medical research. This may include their right to participate and abstain from the research without any hindrance even during the course of medical research.

When participating a child or an insane person in medical research the rules and guidelines on that regard need to be followed accurately. The procedure for getting consent from the parent or the legal guardian need to be followed with.
The extent of the commercialization of the medical research need to be made subject to the limitations emerging from the rights which are recognized by international laws. Commercializing the medical science may not be in the cost of human rights. The autonomy, dignity, privacy and other basic and inalienable rights of the human beings need to be given due weightage. No therapy shall be conducted by the researcher without adequately informing the research participants.

The video recording procedure of informed consent need to be carried out on a systematic manner. The recording keeping and data preservation need to be done based on the prevailing rules and regulations. Appropriate steps need to be adopted to ensure that the results of such uninformed procedures results in strict punitive measures against the researcher/research institutions.

Measures may be adopted to make sure that the research participants are given appropriate compensation for any evil consequences. Being non-therapeutic in nature, if results in injury or any damage, appropriate schemes need to be formulated and followed for indemnifying the research participants. The research participants need to be indemnified in a fair and just manner.

Medical research being non-therapeutic in nature, the research participants are not benefited from the research in all cases. The research participants have the human rights to be benefited from the results of the research arising from the utilization of their body regarding which they have the ultimate right to take any decision.

As any other human being the research participants are also entitled to privacy rights and the right to lead a dignified life. Proper legislation need to be made to preserve these interest of the research subjects. As having the full ownership of their body, the research subjects have absolute autonomy to give consent for any procedure to be performed on their body. The research participants may be made eligible to attain their rights without any restrictions.

By being the owner of the research material the research participants have the right to get the benefits of the utilization of their body material. The research participants need to be entitled of all human rights similar as that of every other individual in the society. The state parties need to ensure that the research participants need to be selected from all sections of the
population. Then health authority in the grass root level or institutions need to educate common man about the implications of the research participation. Proper care and protection need to be ensured when insane children are made part of the research study.

The ethical requirement of medical research indicates that humans may not be subjected to medical research without giving proper information about the procedure. It is becoming a usual practice in the name of health care with the support of highly qualified professionals.

During a treatment a physician can easily justify these as collecting data for meta-analyses for ascertaining efficacy of a drug or to identify the correct dose. There is much risk involved in such actions. If the intention of the researcher is fair the research subject need to know about the risk and benefits involved in the study. Only then the research subject can assess the value of their role in the research study.

The medical research being an uncertain activity the risk involved in it needs to be dealt very carefully. It is not reliable to take the help of any precedents. The medical professionals need not be burdened with the risk involved in the research. Risk that is considered as very high may be confronted with shifting its burden to those who can afford it or by formulating adequate and appropriate means to minimize it.

Fixing liability on the research institutions and there by absolving the researcher from any type of liability may not bring out justice in all cases. Whenever it is clear that the action of the researcher had a remarkable role in constituting any type of injury to the research subject, individual liability need to be fixed. The nature of liability, either criminal or civil may be ascertained depending on the intensity of the reckless action on the part of the researcher.

**Major challenges of medical research with human beings.**

- Most victims of the medical research are from marginalized and vulnerable sections of the society.
- The literacy level of a major percentage of the victims who suffer injury or death is very low.
• Most of the research participants go to these research centres as they get free treatment and preference in medical checkups.

• The individual decision making capacity of most of the research subjects are very limited.

• Blind belief on the health care providers and professionals is another common factor that can be identified from the research participants. They believe that whatever the doctor does is for the welfare and benefit of the patients.

• Non-functioning or malfunctioning of the local health care providers or institutions in educating the common men about the health related concerns.

• Whenever information is provided the majority of research participant is not able to understand the risk factor involved in the research.

• Unable to provide and give proper care and protection to insane children. Many parents of such children depend on whatever incentives given by government or any organizations.

• Even if signed on the informed consent form majority of the research subjects never read or makes any effort to understand what is involved.

• Lack of co-ordination between local health authority and the research institutions.

• Lack of ethics oriented syllabi in medical education and high payment and incentives from private research institutions compared to institutions in government sector attracts young professionals to join research institutions and it leads to unethical practices.

• Non-availability of strict and accurate legal framework making deviant actions of the researcher/research institutions adhering definite liability.

• Lack of proper networking system to contact the research subjects even if enrolled in a medical research leads to non availability of the results. It is not known later what happened to the research subject when there is no proper networking system.

• In a medical research what the researcher is doing is an uncertain activity. Even the
best intended researcher may go wrong and may result in injury or death as the research participants are already suffering from some or other type of ailments.

- The application of the calculus of negligence in medical research similar as that of medical malpractice cases, it is against the principle of justice.

- Lack of a justice oriented formula to identify the amount to be indemnified for those who sustain injury or death consequent to a procedure which is purely non therapeutic in nature.

**Conclusion**

The need of medical services in a society increases the number of medical research carried out in a country. The benefits of conducting medical research may be made available to the society, and then only the society may also contribute its maximum for the advancement of the medical science. If the research results are intended only for commercialization, it may harmfully affect the ethics and morals of a nation.

Health rights are one of the basic human rights. Even though our constitution makers have incorporated several provisions for the protection of health care rights, the extend to which it has been implemented is very less.

Only after consumer awareness movements and protection of rights came, even negligence caused during medical intervention started coming to limelight. India needs to develop a medical a medical jurisprudence of its own. Indian society needs much more hospitals which permit easy access to poor.

We have multidisciplinary hospitals in every city but how far poor and marginalized groups of the society have access to these hospitals need to be considered. India needs to formulate such a health care infrastructure that protects the basic human rights of its population. A vast number of the people in our country are not getting access to the statutory mandate of right to health guaranteed in our Constitution. With the relaxation of the locus standi principle there is a steady growth in the protection of rights of the vulnerable sections of the society.

Law and guidance can provide frameworks for good practice but cannot determine what is
good and bad in individual cases. The researcher need to be able to recognize the value of judgments implicit in their practice and may be able to justify their decisions in ethical terms. Every state has an obligation to ensure the creation of and take measures to sustain all conditions congenial to good health of all citizens even when acting on the principles of utilitarian ethics.

Thus to organize and carry out medical research, with human beings as research participants bears lots of issues that need to get converted into clear, definite and transparent regulatory framework. These are certain suggestions and recommendations on various aspects of medical research involving human beings based on my study.

**Suggestions and Recommendations**

**Role of the ethics committee**

An application to carry out the medical research involving human beings may be permitted only when documents proving the testing of the particular drug in some other species other than human beings are submitted to the ethics committee. The detailed reports of every stages of the testing shall be mentioned.

The rationale of conducting medical research with human beings shall be based on the principles enshrined as basic human rights. The ethics committees need to conduct a risk benefit analysis based on the results and reports of animal experiments before proceeding with testing the drug in human beings.

**Cases of Proxy consent**

The cases of proxy consent shall be scrutinised very carefully. If the said research and the result can be attained by testing on individuals who can voluntarily give consent, then medical research on people with diminished responsibility need to be avoided. If administering the drugs on such people brings any therapeutic benefits, such research need to be encouraged. The medical research involving children shall be conducted giving best available care and protection to the research subject.

The informed consent need to be obtained from the parents or legal guardians. There is a
need of great understanding and an obligation based on ethics and statutory framework for the benefit or interest of the child. Separate ethics committee need to be established in every research institutions for medical research involving proxy consent. Ethics committee approving the medical research involving children may consist of members who are experts in child rights.

**Role of the local health authority**

The researcher shall not go beyond the framework of good clinical practice. All the paper works required for medical research with human beings may be made available for inspection when and where required. The details of the research at every stage need to be recorded and reported and published.

When scrutinizing the details of the research subjects entered by the researcher, the members of the local governments where the research subject resides shall also be consulted. The local health authority shall be furnished with the information that so and so person residing in your locality is being recruited for medical research.

The local health authority need to be informed on the foreseeable risk involved in the said medical research. The local health authority shall be entrusted with the duty to monitor any adverse reactions occurring to the research participants if the research subject approaches any local hospitals without approaching the researcher or the research institution with any ailments which may result in unforeseeable risk. In cases of unexpected level of risk, the said research shall be discontinued.

There shall be proper networking between government run local health authority and the companies or hospital conducting medical research. Transparency need to be maintained in each and every stages of medical research giving the research participant accessibility to the results of medical experimentation.

**Training for researchers based on ethical grounds**
Research subjects need to be protected from unethical research. The institutional ethics committee may recruit officers who are sensible to the basic rights of human beings and those who can address all general concerns pertinent to human rights and welfare of the research participants.

The institutions that conduct medical research may simultaneously train the next generation of researchers. New generation of researchers may be trained as responsible investigators having access to knowledge accumulation in research ethics. The researcher must always keep in mind the goal of medical research- relief of suffering, advancements of knowledge, protection of life and dignity and the advancement of welfare of all individuals in different the strata of the society.

**Literature Review by the Researcher before conducting the study.**

Effective and systematic literature review may be made mandatory before conducting a medical research to avoid repetition of medical research on same issues and matters. Researchers confront with a variety of problems when conducting medical research. These problems may arise from different sectors. To encourage more research appropriate infra structure is very much needed. All researchers may be educated and trained in the ethical and moral principles of conducting medical research.

All these principles need to be included into undergraduate medical syllabus and postgraduate curricula and then reinforced through continuing medical education to all researchers who are conducting medical research.

The medical education curriculum needs to incorporate more ethical principles making the researcher more sensible to human values. The medical research needs to be conducted by those who have through understanding of the issues relating to the proposed research and under the guidance and management of competent, capable, experienced and recognized physicians.
**Publication of Research Results**

The results of the research results may be published without delay, making literature review easy for the prospective researchers. Transparency need to be maintained in each and every stages of medical research giving the research participant accessibility to the results of medical research.

**Disclosure of Risks and Benefits of medical research**

Full information of the possible harms and advantages involved in the medical research need to be made available to the research participants to make an informed choice of to participate or not or to avail treatments which are presently available over the new one. Informed consent doctrine needs to be diluted to absorb Indian values to make it more society friendly.

Measures need to be adopted to ensure that the research participant really understood the risk and benefits involved in the medical research. The women in the rural communities because of the social and cultural arrangements existing in the society may not come forward for any type of research.

Getting informed consent to participate in research in such circumstances becomes difficult. Whatever being the difficulties or differences for giving informed consent, the a physician when acting as a researcher need to keep in mind the ethical and the moral rationale behind the doctrine of informed consent.

The procedures followed to record informed consent may be very clear as well as transparent. Government needs to ensure the safety of the research participant through proper authority with punitive actions.

The researcher may withhold or terminate the research if at any time it has been proved that the continuance of research will harmfully affect the participants. Defaulting research
institutions need to be criminally held liable. The risk, feasibility and the complexity of conducting medical research need to be studied before any medical research.

There may be an assessment of reasonable, probable and foreseeable risk and the natural outcome or resultant advantages to the research subjects and to the humanity at large. Every medical research involving human beings need to evaluate a therapeutic intervention that aims at improvements in health. Only if the society gains knowledge through conducting medical research, exposing human beings to risk involved in medical research can be justified.

**Maintaining confidentiality**

Any data identifying the research participants needs to be kept confidential. Government Health authorities need to be more vigilant while the vulnerable section of the society are being recruited for medical research. Government authorities may act as gatekeepers for enrolling vulnerable sections of the society for medical research.

There may be proper networking between all stakeholders of medical research involving human beings for protecting privacy, dignity, and the right to body autonomy of the research subject. Along with the right to maintain confidentiality of the research participants the rights of the public also need to be maintained.

Details of the conduct of medical research need be accessible to the general public with due respect to the basic human rights like privacy and confidentiality of the research subjects. The administrative procedures relating to medical research involving human beings need to be simplified making the networking between various stakeholders clear, speedy and easy.

**Recruitment of the research subject**

The recruitment of the research subjects needs to be strictly on the basis of a contract. All the
terms and conditions need to be acceptable to both parties. Video recording of the scenes of agreement may prove more helpful in this case. The local health authority needs to be informed on the recruitment of a person from their jurisdiction.

There may be proper mechanism through the local health authority to ensure periodical follow-ups by the research participant once they are enrolled in the research so that their contacts may not be missed throughout the completion of the study. This may bring more transparency to the procedures adopted especially when the research subject is from a vulnerable and marginalized section of the community.

**Procedures of the Doctrine of Informed consent**

Justice shall result from employing the doctrine of informed consent. The material facts regarding the advantages and the disadvantages of the research need to be explained to the research participants in an understandable language. The formula which is recently adopted in India to record the informed consent procedure may prove good and result in justice only when the members present while recording the procedure are educated and have the knowledge about the pros and cons and the ethics of the research.

A member from the local health authority also needs to be there during the recording. This may make the research participant more comfortable during the procedure. The method and the procedure for preserving the electronic data also need to be made clear. Where it will be preserved, how long it will be preserved etc need to be answered.

The rules relating to the confidential nature of other electronic data need to be made applicable in this case also. The informed consent procedure needs to adapt to the cultural and social background to which it is being applied.

**Compensating research participants**

The scheme for the compensation needs to be more victim friendly as medical research is
non-therapeutic in nature. In the instances of happening of death/injury to the participants of research the terms of the contracts dealing with compensation need to be strictly followed. The regulatory frame works need to be apt and prompt enabling more research studies facilitating advancement in medical sciences.

The government must see that there is a proper coordination of advancement of medical science and protection of human rights. There is a need of specific legislation with a framework to evaluate the amount of compensation payable to the research participant specifically for medical research. A government run insurance authority to indemnify the medical research participants need to be set up giving them a choice between private insurance and a government run insurance scheme.

Medical research with herbal remedies

There may be bias regarding the introduction of herbal remedies and medicines depending on the social and cultural background of the countries where it has been introduced. This can be overcome by ensuring a properly designed study design and by including proper and accurate group in the research. As far as possible, the medical experts of the place from the drug originates may be contacted and consulted before conducting the research. Results and benefits of the proposed research may be shared with the community where the research is going to be done.

The material factor of the research is well trained researchers whom can be considered as the ultimate guarantee for the safety of the research subject. The research participant’s welfare and treatment may be done as per needs only when the researchers are properly trained and experience. It is also necessary that the ethics committee constituted for review of ethical standard of herbal studies may be vigilant similarly as that of any other conventional medical research involving human beings.
Rights of the Researcher/ Research Institutions.

Rights of the research institutions also need to be protected. False and baseless allegations and media reports need to be curbed for unhindered development of medical knowledge. Private complaint may not be accepted unless the aggrieved person has furnished in the court evidences which is a reliable certification of another physician/ researcher to strengthen the allegation of recklessness or negligence committed by the accused researcher / institution.

The agency which is investigating may before initiating any action against the researcher who is under the allegation of reckless, inadvertent, or negligent act may get an impartial and authoritative opinion. The physician providing the opinion need to be one qualified in that area who can provide an opinion which will be impartial in every aspects.

The arrest of the researcher accused of negligence may not be in the same manner as that of a negligent doctor, unless that is mandatory for carrying out the investigative procedures or collection of evidence. For the non – compliance of instructions given by the researcher by the research participants and for the resultant injury the researcher alone may not be held liable. Medical research consisting of human beings being a crucial factor for the advancement of medical science need to be accommodated along with protecting the rights of research participants.

\[1\text{ Ibid.}\]
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