ABSTRACT

Medical research is essential for the health and well-being of the humanity and for the advancement of medical science. There are many national and international guidelines and principles ensuring protection of the research subjects who are enrolled for medical research.

Guidelines and ethical requirements are not mandatorily followed as there is always a vast difference between ethics and compliance. As a result there are many violations of basic rights of the human beings while conducting medical research. India doesn’t have a balanced and strict regulatory framework for medical research involving human beings.

All medical research conducted in India may follow ICMR guidelines of 2000 as per the specifications given by the D&C Act. 2002 MCI Act also mentions that all medical research conducted need to comply with ICMR guidelines. The MCI Act has the authority even to initiate punitive actions. So it is mandatory. Even though the guidelines may be mandatorily imposed by using such a provision, it is not done, as there is no express legislation relating to medical research using human beings in India.

The Drugs and Cosmetics Amendment Bill has been introduced in 2013 with various changes in the regulatory mechanisms of the conduct of medical research involving human beings. It is necessary to implement specific laws for the protection of research subject.

The chapter I of this thesis gives a general introduction to the medical research involving human beings. Several illustrative models are narrated to highlight the intensity of the issue of using human beings in medical research without following the ethical, moral or legal requirements for the participation of human beings in medical research. Chapter II of this analyze various literatures on this matter done by different scholars around the world and evaluate several instances in which human rights are violated in the name of medical research.

Chapter III examines various ethical theories based on which the involvement of human beings as research participants in medical research for the benefit of the humanity at large is rationalized. Chapter IV discusses the doctrine of informed consent theory, the applicability of this foreign originated theory to the social, cultural and vulnerable population in India.
Noncompliance of the principles of informed consent and consequent violations of basic human rights and how various jurisdictions tries to preserve the rights of the research subjects are discussed in Chapter V.

With the advancement of health care sector as a big industry the legal, commercial, indemnity and intellectual rights protection of medical research need to be discussed. Chapter VI deals with commercialization and legal control of the medical research. Prevailing legal framework of medical research in India is discussed in Chapter VII.

Pharmaceutical industry is very much benefitted by the conduct of medical research. Pharmaceutical industries or rights of the research institutions also need to be discussed. The various drawbacks for conducting medical research in India are also discussed. Theoretical basis of tortuous, contractual and criminal liability to identify the appropriate liability in each case is also discussed. Constitutional Provisions, sale tax issues relating to medical research involving human beings are also discussed. Chapter VIII gives some suggestions and concludes the thesis.