CHAPTER- 2

LITERATURE REVIEW

Good health is crucial for human beings. State has an overreaching duty to safeguard the health of people. Origin of the state’s duty to ensure protection of its citizens may be traced backed from the period in which people collectively transferred some of their liberties in exchange of a guarantee that the state will ensure protection for their wellbeing.

Good health doesn’t mean a mere state of not having any ailment. The state has a duty to provide its citizens new and improved health care facilities. Medical research is for the progress of medical science and for benefitting the humanity.

The concept of justice and morality is always a question when human beings are made use in medical experimentation. There are many theories based on legal and political issues revolves around the question that whether the concept of justice is a component of law or a moral justification of a judgment based on Law.

There are many reasons to prove and support the argument that justice is one of the parts and
parcel of law and cannot be separated from law. The concept of justice is what the law aims at; justice is that which the lawyers argue for, justice is what the judiciary adjudicate. Law involves certain intellectual complex mechanisms through which justice to a particular case leads to justice to the world at large.

The concept of human liberty as developed by the advancement of human civilization is related to the rule of law. The essence of freedom can be enjoyed in its fullest only when people understand the law and have trust that the government abide with the wordings of the law.

Law evolves from experiences. History reveals many unethical practices in the name of medical research. It is through those legal framework on medical research with human beings have evolved. Unethical medical research was conducted by physicians based on certain norms which they believed to be ethical which later on upheld by judiciary as unethical.

Thus the legal framework on medical experimentation with human beings evolved and developed on the basis of a rivalry between different norms. A standard behaviour or norm may evolve as law or get enforceability when on analysis it provides a better cost-benefit ratio to the society. In one sense a legal framework for medical research with human beings is a type of risk reducing strategy. Formulating or setting norms with a view to limit or restrict risk.

When some violations occur to the existing laws and regulations, the judiciary comes into picture. Through many interpretations given to the existing rules and regulations the judiciary tries to accommodate each and every situation arising for adjudication even though there is no specific law on issue in question.

Through employing the strategy of interpretation the judiciary tries to evolve a logical reasoning for every matter. Thus the Indian judiciary in several cases have given various interpretations to the existing health care rules and regulations to adjudicate health care concerns. These judicial pronouncements forms a very good literature to review.

In Municipal Council, Ratnam Vs. Vardhichand & Others (1980) Justice Krishna Iyer made the judgment that as per the provisions of Article 47 the state is under a mandatory duty to
make appropriate measures for the improvement and protection of public health. He opines that adopting measures for proper and healthy environment is one among the primary duty of the state as health of the individual is the essential component of a meaningful life.

Exposing human being to unreasonable risk without following adequate rules on those issues forms a violation of constitutional provisions. The wordings of these judgment may be extended to medical research with human being.

CESE Ltd Vs. Subash Chandra Bose, (1991) AIR 1992 SC 573, in this case the court formed an opinion that health of an individual being a right protected by the state acquires the nature of a fundamental right. In this case court relied on several international documents and came to the conclusion that health rights forms the category of rights that are fundamental. The court opined that health means not a condition without any sickness. The court specified that medical facilities which the state provide need to ensure a changeless manpower.

Such resources may be made useful for the economic, political, social, cultural and overall development of the nation. Good health ensures the workers to enjoy the benefits of their own labour. Even if for the benefit and welfare of the humanity subjecting a human being for medical research without his consent is against the constitutional principles.

Any ailment or injury resulting as consequence of participation in medical research need to be compensated as a part of measures adopted for social security. The court also specified that safeguarding good health is the prominent constitutional objective which is possible only through a proper networking and interaction of several factors in the society.

Mahendra Pratap Singh Vs. Orissa State. (1997)

The court in this case discussed about efficient measures for the functioning of Gram Panchayat . The court opined that life may achieve any good accomplishments only with a healthy body. This judgment upholds the health care rights of a large population.

CERC vs. Union of India (1995) The court specified that, the right to protect and preserve
health and availing state benefits for the health care is an essential component of the right
 guaranet hed under Article 21 of the constitution. This is a minimum criterion to be fulfilled for
 the protection of dignity of an individual.

When we expand the principle adopted in this case to medical experimentation with human
 beings, it protects the rights of the human research subjects against uninformed procedure
 conducted in their body. Subjecting a human being to any therapy or procedure against his
 will is a violation of his right to have a dignified life as guaranteed in our constitution and as
 interpreted by our judiciary.

State of Punjab Vs Mohinder Singh Chawla (1996) The court highlighted the obligation of
 the government to provide health care amenities. The judge explains that the obligation
 emerges from the constitution. In this case the court directed to reimburse the amount
 spend by the government servant towards expenditure incurred during any treatment of his
 ailment.

Dr. Suresh Gupta Vs. Government of Kerala (2004) 6 SCC 422. The court in this case opined
 that criminal proceedings against a medical practitioner may be initiated only in cases of
 gross negligence. The court specified that medical practitioner may not be held liable for
 every unwanted results or consequences occurring during the course of medical interventions.
 If we extend these principles to the medical research involving human beings, the
 characteristic features of medical research and medical practice is different.

The main distinguishing feature being the non therapeutic nature of the medical research.
 When subjecting a person to a procedure where the said person does not have much benefit
 from such therapy, the standard of care ought to be adopted by a researcher is very high. The
 court in this case established that the criminal liability may not be fixed if the patient’s death
 resulted because of an accident or an error.

 The judge in this case pointed out the consequences of any complaint or suit filed against a
 medical professional. The impact of any legal actions and proceedings on his career.
The court opined that in the instances of medical negligence only after an enquiry conducted by the police and after accumulating required and essential materials of evidence, proceedings may be initiated against the medical professional. If we stretch this judgment and interpret the wordings to make it applicable to medical research involving human beings, more caution is needed from the part of the executive as well as judiciary in investigating the case.

The court pointed out that along with the features of civil liability for negligence, in criminal negligence it is essential to prove a type of rashness in the conduct of the doctor that he did the act knowing the risk and danger inherent in the act and was aware that injury is imminent. The amount of negligence what is needed is gross and not mere error of judgment.

ASIAD Construction Workers Case, AIR 1982 SC 1473. The state has an obligation which emerges from the constitution to guarantee that there may not be any infringement of fundamental right of any person, especially to vulnerable sections of the community as they are incapable to wage a legal war against the powerful opponents.

Samiran Nundy (2005) The author discusses about various hurdles involved in conducting medical research in India. It is greatly problematic to experiment medicines in countries in the western side of the world with stringent laws on medical experimentation involving human beings.

The tremendous measures for protection and provisions for damages and the factor of less population of western countries makes the enrolment of participants of research subject moderate and costly. Thus many pharmaceutical and research institutions are now carrying out research in several developing countries.

Sinha G (2004) The author discusses about the reasons for big pharmaceutical companies to invest money in India to conduct medical research. Vast variety of genes, greater number of people who are not exposes to other drug use, easy access of vast number of patients in most disease categories, excessive number of hospitals and doctors who speak English, and doctors with post graduate qualifications from abroad, primarily from Britain or the United States are some of the factors which influence large pharmaceutical companies to set their research centres in India.
Fortner’s Case (1935) the judge laid down the reason for conducting medical research. The judge explained that, if the medical science is to progress, medical research is an essential factor. Originally US courts considered almost all form of medical research as medical malpractice, because these practices are different from usual treatment or therapy. After 1935, the courts started giving some legitimacy and explicitly addressed issues of medical research involving human beings.

Mark Hochhauser (2006) If the injury to research participant is caused due to the medicine under experimentation or improperly conducted study process and has not caused the damage by failing to adhere to the mandates of the researcher, the sponsor of the research may indemnify for the reasonable medical expenditure essential to treat the injury. The research subject cannot waive any right recognized by law by being a signatory to the informed consent form. The research participant who suffered injury need to prove that the injury is caused not because of their fault.

Indrayan (2004) The author explains about the type of research conducted with human beings. He opines that, almost all research conducted with human beings are empirical. It is based on evidence than hunches. It follows a series of specific steps. It doesn’t have any short cuts. Collecting evidence and analysing it may follow a carefully made protocol. The modern medical research needs biostatistical tools to arrive at a valid finding. The individual carrying out the research may have an adequate knowledge and skill to be really effective. These endeavours of medical research may be consistent with the accepted research ethics.

Fukuyama (2002) discusses about bad effects of biotechnology. He explains that, while people are concerned about safety, undesired consequences, unforesen costs, and the like but the grass rooted concern that people express about biotechnology is not utilitarian in nature. Rather an apprehension that, biotechnology may cause and result to lose our humanity. The author expresses his concern for unscientific and unethical experimentations and the aftermath of those researches on humanity.
Mary Warnock (1993) the author discusses about the technological development and the disadvantages arising out of it. The author opines that advancement in scientific knowledge made possible all kinds of things possible that where not possible during earlier days. An ethical question posted in a strict utilitarian structure is, whether the advantages proposed by the procedure are outweighed by its foreseeable disadvantages and harm? There need to be a proper evaluation of the risk as well as benefits arising from the technological developments.

Cassel (1995) discusses about the obligation of the researcher to the research subject. Non abandonment of the research subject is the central ethical obligation of the researcher. There need to be a commitment on the part of the researcher. To take care about the research subject and also to provide treatment and solution to problems and ailments of the research participant forms the central obligation of the researcher. When all these obligations are fulfilled the conduct of the researcher or the research institutions becomes an ethical one.

Katz (1993) opines that, the need for codification and regulation of law relating to medical research in man was a response to the revelation that adhering to the ethical conscience while conducting research, inculcated in the physician – investigators during their medical education, is insufficient. History reveals that, the researchers acted without any ethical considerations and failed in safeguarding the rights of research subjects.

Annas (1992) the author opines on the nature of Nuremberg Code. He considers that Nuremberg Code is a rigid set of legalistic demand. He makes a comparison between the Nuremberg and the Helsinki as concludes that Helsinki is an ethical one.

Perley (1992) discusses about the nature of Nuremberg Code. It is a totality of medical morality, at least as affirmed even if not always practiced. It expresses putatively universal standards. Informed consent is one of the main factors involved in Nuremberg Code.

The Nuremberg Code was not just about consent. It also introduced the standard of
“necessity”. A research may be conducted only when it may be to yield fruitful results to the society. The intended results of the said research are not procurable by any other means or methods of study. The Nuremberg code also points out that the research may not be random and irrelevant in nature.

Ryan (1993) opines that, Justice deals with equitably choosing the research participants and distributing the risks and advantages of entering into a medical research procedure. Justice guarantees the inclusion of different communities for evaluating medical research with human beings. The purpose of justice necessitates giving compensation for any injury arising out of the research. He suggest that power is legitimized and rationalized only when justice emergence from the authority who have the power.

Tauber (2001) the author discusses about the principle of Justice. He opines that the principle of justice is essential when analyzing the issues like, exercising the autonomy, the limits of autonomy, role of justice etc.

Vanderpool (1996) opines that, addressing the needs of the community envisages, that community may be added as a fourth principle along with the three other. He opines that it is better to interpret all these principles in a communitarian approach rather than giving merely an individualistic approach.

J. Wilson (2007) the right to autonomy gives a person the liberty of self-determination. It mandates an individual to take responsibility for his own decisions. Thus autonomy of an individual has a connection to the factor of consent.

Leonard H. Glantz (2002) The duty of a researcher is usually considered as the standard of care which he owes to the research subject. A researcher may be considered as negligent by a court of law if he does not uphold the standard of care in that particular situation. This peculiar connection between the person doing the research and the research participant may bring certain unavoidable duties. The breach of those duties forms the basis of an action in negligence.
Jerome Hall (1947) the author explains that in intention, the person doing the action envisages the harm in question not in the manner that he intends it, but in the manner that he had chosen it himself, foreseeing all its consequences he had intended to bring about the intended consequences. On the other hand in describing the defendant’s state of mind as negligent, it means not only that the behaviour in question fell below a certain objective standard but also that it was not intentional or recklessness.

**Ethical concerns of medical research**

Johan PE Karlberg (2010) The author opines that ethics answers the rationale or reasoning for justifying the principles of morality. Ethics and morals are very much interrelated. Ethical principles emerge from philosophy and religious writings. Ethics of a society is embodied in the culture and life style of every society. Ethics and the morality of a society judge the nature and the type of the society. With the advancement of biology and medicine a separate branch known as bioethics also developed around 1960s. It deals how health care personal may deal with his daily pursuits in an ethical and moral manner.

The percentage of value which the society gives to human life. How it protects and safeguards the rights of its citizens. It fixes certain duties and responsibilities on both the medical professional and the consumers of health care sector. Bioethics answers the ethical dilemmas in the interdisciplinary areas of physiology, biotechnology, medicine science, politics, legal studies, philosophical studies and theological studies.

Fullbrook (2007) The author discusses about the importance of ethical theories and knowledge. He opines that, along with professional development, the researchers need to accrue and expand their knowledge and review the ethical theories and guidelines. The conduct of the research may be beneficial to the society only if it is rationalized based on ethical and moral principles.

David N. Weisstub (1996) opines about how to choose priorities while making health care
decisions and to arrive at ethical solutions. He considers that, it is through the importation of bio-ethics principles that research ethics is functioning as a way of perceiving moral thresholds and decisions about priorities. These principles form guidelines for such decision making.

James purtchaell (1988) the author is of the opinion that the practises shows that people who are favouring the research on foetal tissue is very much supporting the practice of abortions and intends to produce some profit out of it. He discusses the interconnection between these two practices. He explains that the ethical dilemma behind the both are same, the value or status attached to the foetus.

Robertson (1988) the author discusses about certain divergent views about the authority of the women to donate the foetal tissue materials for research. It is being stated that, there are many writers favours the opinion that, when one decides to undergo abortion abandons her right to decide on what to do with the dead foetus. After taking the decision to abort there is no right to claim possession or the ownership of the dead foetus.

The author opines that it is better to take a balancing approach. He suggests that it is ethical to guard the feelings and interest of the woman. She may be provided an assurance that the remaining of her kin are given due respect. She shall be given priority in taking a decision on what shall be done with the remaining of her body.

John R Williams (2008) maintains the opinion that, the issues relating to medical experimentation with human beings as the research participants are somewhat complex. It is not that much simple as it appears. Difference of opinion prevails over many ethical areas. Funding of the research, therapies to the research subjects whenever needed, duties of the researcher, rights and preferences of the research participants etc are some areas on which there arises differences of opinions.

Lewis (1996) the author discusses about the ethics and morals behind embryonic stem cell research. Practical approach may allow fabrication or overstatement to promote claims favouring embryonic stem cell research. This approach is to move beyond what is presently a
limited amount of information in this new area of science. They conclude that the reasoning behind justifying destruction of embryos is to benefit the society.

In practical approach the paramount factor is scientific progress in the hands of experienced ethics abiding professionals. The author concludes that the superiority power of human beings over nature has turned to the direction that some men uses the power of the nature for the advancement of the medical science and technology by suppressing the rights of the vulnerable human beings in the society.

Willam P Cheshire (2008) the author believes that to recruit some of the youngest of our kind for medical research resulting in their destruction goes against the ethical line of non malfeasance. It may not rationalize the meaning of human procreation.

He maintains the view that, even if it is recognized that, embryos of human beings deserves dignity as being a part of human body having life, controversy arises with regard to the nature of respect and the strength of protection required at various stages of development of the embryo. When it comes to the legal right and ensuring legal safeguards there is no common rule. There is no strict application of law as there is divergence of opinions from various religious and social backgrounds.

Nanivadekar (2004) Ethical principles or standards are relevant to guide decision makers. It assists in judging their action. These principles provide a basis for moral accountability. An ethical principle gets power only when it is enforceable by mandatory force. Through such force it gets an inherent nature of law.

Something the human beings have been following and were accepted by the society from time immemorial. It changes along with the changing needs of the society. The author concludes that it is relevant to medical research because during the process of research the research subject may or may not benefit, or sometimes get harmful effects.
Edmund D. Pellegrino (1981) the author makes a comparison of ethics and law. He opines that ethics when compared to law is a fine balancing made by men for the voluntary assumption of obligations.

This voluntary assumption is very much mandated by the very features of some relationships between humans. Only some of the ethical requirement gets the enforceability of law. Ethics envisages a higher ideal compared to law. This higher ideal and motivation is mainly because it is not guaranteeable. Only those ideals which are guaranteeable attains the nature of law.

Taylor (1995) regards ethics as a socially rooted knowledge based on practice that has a fair and rational reasoning. Rationality to the ethical principles comes from the fact of acceptance to those moral values given by the society. It is not always based on rational calculation. Ethics followed in a society shows the nature of the society. As it is normally embedded, ethics envisages involving in actual situations and a feeling of membership in a particular social group.

Drowkin (1978) suggests that utilitarian reasoning invites a principled resistance to the utilitarian pragmatism of the kind that is familiar, not just in bio-law and bio-ethics, but right across the board of practical affairs.

Hans Jonas (1969) reflects on the reason for conflicts relating to research ethics. He says that when experimentation was conducted with inanimate objects there was not much hue and cry about ethical and moral principles. When medical researchers started research involving human beings the genuineness of the procedure has lost and the issues of consciousness emerged.

The author opines that a review of literature on the medical research ethics depicts that the issue is, rights of the person versus the rights of the society. He says advancement of the society is only an alternative purpose of action and not an essential assurance. For conquering triumph over different ailments the society may not allow the erosion of its ethical and moral values. In the name of advancement in medical science the humanity may not loose dignity.
and basic human rights.

Hans Kelsen (1960) The author makes a definite categorization of the concepts of law and justice. He opines that law can be fair and unfair based on religious and social reasoning. It is justice which makes a law generally applicable to all. It is injustice if a law is not applied similarly to another same set of facts.

He gives certain justifications for his claim. One claim is based on the nature of certainty of law and justice. Law is certain but Justice is not certain. The issue that whether a specific law is just is considered outside the legal system. Justice mandates that same law may be applied to all cases that falls within the same category.

Emanuel EJ (2007) the author opines that it is essential that a physician may carry out a cost effective health care service. Only with such service, justice may be rendered properly in a welfare state. The author points out some requirements for carrying out a cost efficient health care practise.

Proper information about the possible range of expenditure which may incur for the treatment, therapy or the research in that particular jurisdiction may help a lot to identify the cost of the health care service. Every person both the service provider and the consumer may have the knowledge about these facts.

An independent organization may be entrusted with the duty of facilitating this information. The health care framework may be more efficient if this organization which is an independent one may be publicly funded. With the advancement of medical science specialization in each parts of the human body is presently available. The growth of the medical science may be made available to all sectors of the population.

There is no need to waste money and time for diagnosis by a general physician when speedy diagnosis and appropriate treatment is available with the help of a physician who is specialized in that particular field. There is a need of proper networking and formulation of appropriate strategy for providing a cost effective health care service. The doctors also need
to be provided with incentives for ensuring an effective service.

Pauly MV (2005) the author discusses about the growth of expenditure in the health care sector. He opines that the expenditure in the health care has increased too much when compared to other sectors of economy. The author attributes the reason for this to scientific and technological advancement.

The author is of the view that the development and tremendous advancement of insurance sector facilitating to indemnifying the consumers is one among the many reasons for the growth of health care sector. New and improved medicines, therapies and medical procedures have positively changed the lifestyle and quality. The author also suggests that unproductive methods and procedures need to be replaced from the health care system for proper and efficient functioning.

Nancy King (1995) explains about research as something formulated to evaluate a hypothesis and is carried out on the basis of rules of the protocol. Therapy or medical practice is something which, formulated to give advantages to that particular patient and is amenable to appropriate adaptations whenever it is needed for the interest of the patient.

Ruth Macklin and Susan Sherwin (1975) examines various ethical theories of medical research. A comparison is made on the theories of Kant and Rawls. In the instances of people with diminished responsibility the author is of the opinion that application of Kantian philosophy is very much stringent. The calculus of utilitarianism may easily contribute to exploitation of marginalized and vulnerable sections of the society.

The author opines that Rawls principle gives us a yardstick to evaluate how much a society follows the principles of justice. A society in order to be considered good may also facilitate certain standards which brings happiness to each and every. The happiness of an individual may not be destroyed on the ground of utilitarian reasoning.
Even though the authors favour the reasoning of justice propounded by Rawls they are of the opinion that a single ethical theory may not be effective in dealing with the ethical and moral controversies surrounding the medical research involving human beings. The author suggest the application of a mixed factor ethical theory which has a combination and features of all ethical principles to accommodate all philosophical views.

Gillions (1994) opines that, the doctrine of respect for individual autonomy, showing beneficence, non malfeasance and following the principles of justice does not provides any ordered rules. These principles may help a researcher to make decisions when reflecting on moral or ethical issue that arises during a research activity. Among these principles, principle of respect for autonomy is regarded as first among equals, because it is the necessary component of the other three.

Cook RJ. Dickens (1994) the author opines that in medical profession the theory of confidentiality can be traced from the old Hippocratic Oath. This theory forms the cornerstone of the medical professionalism. The basis of the theory is that without fear and any discomfort anyone coming into contact with a medical professional can disclose any information which is very confidential and may not be known to the general public. If known to anyone other than the medical professional it may prejudicially affect the interest and right of the patient.

Confidence between the physician and the patient is the basis of this theory. It is on the background of this theory that the diagnosis, treatment, and cure of the ailments are normally possible. Without a trust between the patient and the doctor concerned a proper care and comfort from a health care service is impossible. It is the duty of the physician concerned not to disclose those information received in a confidential manner. The disclosure of such confidential information is against moral and ethical principles.

Barber (1973) observes about the professional responsibility and social accountability needed for the researchers. Self regulation plays an essential and important role in forming a responsible researcher. Through the syllabi of the medical education medical professionals
need to be trained to form an attitude based on the accepted ethical and moral principle in their conduct.

Beecher (1966) explains the growth of medical investigators. He opines that the value which the society gives to medical research involving human beings combined with the growth of medical research as an attractive profession from the viewpoint of young physicians may result in the separation of interest of science and the interest of research participants.

Arthur Caplan (1988) examines the validity of unethical medical research from a scientific viewpoint. He opines that a finding in order to be beneficial to the society need to be conducted in an ethical manner. The medical science should not accept the results of an unethical research however great and beneficial it is.

Michael J Malinowski (2002) the author explains his views and his rationale for taking such opinions on research with human embryonic stem cells. He also addresses the impact of laws on this issue. He discusses about the approach he takes to issues connected to law and ethics related to medical science and practice. He argues that he always initiate an approach which is application oriented. It gives priority to real facts based on experiences of life. The impact of a theory on the system and culture of life generally accepted today.

According to the author such an approach may help in identifying, analyzing and solving the problem much efficiently. He also examines the responsibility of the health care professionals to be open and self aware. He argues that the duty is moral than professional to fill the gap between the law and reality. He concludes that meaningful framework is essential for the effective dispensation of health care services.

Rothman KJ (1994) The author races several opinions on the regular use of placebo in medical research. His concern revolves around the use of placebos when there is alternative efficient method of treatment or procedure of treatment available for that specific health condition or ailment. He suggests that such use is totally against legal and ethical rationale.
The use of placebos may be justified when there is no effective treatment for that particular ailment.

The author points out the inherent difficulty as how to ascertain effectiveness. Effectiveness of the placebos over the available one. The author also points out that use of placebo is relevant to determine the correct potency and effectiveness of the actual drug.

Another issue is based on the use of placebos is the delay in the use of actual treatment and the resulting harm from non medication. This issue becomes more problematic when the research is a long term research. He also opines that the effects of the placebo are difficult to ascertain when the dropout rate of the research participants is very high.

Hans Jonas (1965) is of the view that protection for human subjects might lead to slower medical progress, but he accepts this delay as a reasonable price to pay for the maintenance of human values. The medical research involving human beings is a process which needs to be done with utmost care and precaution. Every phase may be proceeded under strict legal and ethical supervision.

The rights of the human beings may not be suppressed for the advancement of medical science through medical research. The medical research is a time consuming process. The time taken is justified as a cost incurred for taking measures for protecting basic human rights and values.

Packer M.J (1989) Theories of ethics stands on concerns and values that furnish and constitute a framework in which conclusions about the justifiability and non-justifiability of actions may be arrived at. The values, ethics and morals of the society are reflected in each theory. Theories are considered as a guiding force to judge what is right and wrong in a particular situation when decision making need to be done while evaluating several categories of interest.

Weisstub (1996) considers that, sometimes protecting human subjects involved in medical research may create sensitivity. Advocating for the moral and legal fictions may damage the trust in the integrity of science. It may also create intentional or unintended
obfuscations in professional capacities and outright violations of subject’s privileges. Protecting human subjects is not only a commitment to fundamental ethical principles but also a duty to the whole society.

Bertram G. Katzung (2001) the author illustrates how medical research with human beings may be utilized to satisfy the needs of the health care sector. He narrates the part of medical research in the development of pharmaceutical industry and medical science.

He traces the growth of medical research involving human beings from the period of 20th century and how medical research has contributed for the improvement in the life style of the people. He opines that for conducting research by the academicians has very much supported and encouraged by various agencies of the US government.

He opines that the pharmaceutical companies have also contributed financially to the academic community. The author opines that pharmaceutical sector is an example of meaningful blending of scientists belonging to science discipline, biology and physics. The author highlights and concludes by pointing out the relevance importance and the need of cooperation, collaboration and effectiveness of networking between multidisciplinary team for developing a useful drug.

Katz (1993) explains that there is a common agreement that, sacrificing the rights of the individual research participant for benefiting the humanity need to be minimized. The liberty and privileges of men are same and similar for all. There is no meaning in scarifying the life of one for many others but, medical research involving human beings cannot be avoided altogether as it is performed for improving the health care facilities. Investigators need to take special care to ensure that risks are minimal when human beings are involved.

Roop Gursahani (2009) discusses about the inclusion of people with diminished responsibility in medical research. The author is of the view that recruiting people with diminished decision taking power in medical research is ethically and morally acceptable only if the ailment for which the experimentation need to be done may be answered with such
category of individuals. The author mandates that it is essential to prove that the particular research has therapeutic value to the research subject.

Marilyn J. Field and Richard E. Berman (2004) discusses about including children in medical research. The authors opine that children shall not be completely limited from medical research. Even though it is ethically acceptable to involve children for medical research, paediatric ailments and the medicines for those may be experimented only with the inclusion of children placing undue burden on children is not ethically proper. A systematic, efficient and well arranged protocol is an essential factor in medical research which includes children.

The author is of the opinion that a properly administered, well functioning system with enough facilities is pertinent. It is essential to fulfil all moral and legal requirements while safeguarding infants, children, and adolescents. Efficient execution of strategies to safeguard child research subjects necessitates suitable proficiency in child health care in all levels of the research.

The author concludes that an expertise information and knowledge of infant, child, and adolescent physiology is essential. The evolution and growth and other paediatric needs may be properly understood only when research is done in children but may strictly adhere to strict ethical considerations.

Ruth Macklin (1999) opines that, appreciating the rights of the individuals is commonly and naturally assumed and considered as the ethical doctrine formulated to safeguard and protect the lawful claims of human beings of medical and behavioural research. The rationale of accepting the rights of the individuals is reorganization of the principle that everyone has the right to determine about oneself. The author explains that, it indicates that everybody has a right to say whether to participate or not in medical research.

The author raises concern about those with diminished responsibility. He says that those who have no legal right to give a valid consent may be safeguarded. Taking consent from an individual or from the legal guardian or the natural guardian is one way that health care system demonstrates respect for individuals of such category and accepts the significance of personal autonomy.
The author also examines the feasibility of relocating a doctrine as it is which is rationalized in one cultural background to other culture where it may not be rationalized. He criticises this approach as an ethical development in its worst expanded form. According to him the informed consent doctrine may be reformulated to suit to the cultural and social context in which it is to be applied.

Levine (1999) explains that the medical researchers frequently contravene some of the terms mentioned in the Helsiniki Declaration. He also asserts that the provisions of the declaration are not in par with present concurrent ethical principles.

He explains that the Helsinki needs not be amended to suit to the present day acceptable ethical standard. He argues that the declaration of Helsinki is incomplete. He points out the reasons as; the declaration is not in tune with present ethical standards there are violations of the rule which fails to bring credibility to the provisions of the declaration.

Cook RJ and Dickens BM (1991) consider that Ethical principles, theories and guidelines for medical research consisting of human beings are centred on a twin purpose. First to respect an individual’s right to take a decision voluntarily, and secondly the protection of marginalized and vulnerable people from exploitation in the name of medical research.

**Informed consent and medical research**

Johan PE Karlberg and Marjorie A Speers (2010) discusses about the risk and benefit arising from medical research. He says that both risk and the benefit very much depends on several factors like, which phase the research is, the nature of medicinal agent experimented, the ailment under research, the presently available therapy and the nature and quality of care given.
Richard E. Ashcroft (2003) elaborated on different strategies which need to be adopted while obtaining informed consent from different sections of the society. He opines that the strategy adopted for the mainstream section may not be same for the marginalized and vulnerable section of the society. The plan of action to obtain informed consent may be carefully designed. He explains that the objective behind these measures is to build and develop public trust in the conduct of medical research.

Meisel (1977) discusses that typical informed consent issues emerges when a patient come across any injury which resulted non negligently as an outcome of a therapeutic medical procedure. He explains that the consequence that is non negligently resulted may be because of the physiological disparity from the principles or specific sensitivity of a patient.

Ruth Macklin(1999) opines that, some scholars looks informed consent theory and judges its applicability from prevailing cultural differences in a society. They argue that this theory may be practicable only in the west. It will suit only for the socio cultural background of the western countries.

The author argues that, rationale behind considering the informed consent as an ethical requirement is that research subjects may be subjected to any form of compulsion and atrocities even if they no injury results. It is essential to analyze the nature and the methods of informed consent, the difficulties arising while obtaining informed consent for the purpose of medical research.

Beauchamp (1989) the author discusses about the interrelation between the notion of body autonomy and the concepts such as privacy, voluntariness, self mastery, choosing freely, the freedom to choose, choosing one’s own moral position, and accepting the responsibility for one’s choices.

Appelbaum PS (1987) opines about the importance of the doctrine of informed consent in medical research. The author explains that, the code of research ethics formulated in Nuremberg to judge the conduct of the doctors during the research procedures was uncompromising about the moral and ethical importance of the doctrine of informed consent.
A medical research may be morally and ethically justifiable only when it is conducted after obtaining proper informed consent from the research participants. Conduct of medical research without giving adequate information about the risks and the benefits of medical research to the research participants is a blatant violation of the basic human rights of an individual. These thoughts and debates have shadowed the development of biomedical ethics, in which the doctrine of informed consent has come to occupy the core and central position.

Dworkin (1988) discusses about the autonomy of every individual in taking decisions about his body and life. He constructed the expression of autonomy to include liberty, freedom, dignity, and independence as critical reflection of decision regarding one’s own body.

Johan PE Karlberg and Marjorie A Speers (2010) gives instances of research participants were needlessly injured as part of medical research. There is also lots of successful research conducted. He opines that ethics on medical research involving human beings says about balancing of risk and benefits.

The ethics demands that the research participants may not be subjected to unwanted risk resulting in harm. The ethics also mandates to restrict unwanted hindrances and lagging and delay of the medical research when it involves the involvement of humans as research subjects. The author concludes with the opinion that, the research may be structured in such a manner in which there is only very minimal risk.

Tobias JS, Houghton J (1994) examines how much information about the procedures involved in medical research may be revealed to the research subject. He opines that still many people argue that matters have proceeded much far and the straightforward revelation of the material factors involved in the research procedure to the research participants who are competent is not always warranted.

Lidz cw .Appelbaum PS, Meisel A. (1998) discusses about approaches in the informed consent procedures. The research subject needs to understand the actual effect and foreseeable result of the proposed intervention. The research subject thus may be properly informed. Informed consent is obviously a patient centered one. The research participant need
to understand and analyze the information provided to them by the researcher before consenting to a procedure. From a researcher point of view it requires disclosure of two major types of risks. Firstly it is the general and significant risk and secondly it is the specific and particular risks applicable to the patient. The first comes in the category of objective or reasonable patient approach and the second in the subjective or particular approach. In fact the concept of informed consent combines both types of approaches.

Fulford K, Howse K (1993) discusses about the theory of informed consent. He explains that it fails to apply to the cases of who cannot give consent because of any incompetency and also in cases of the researcher uses only data collected earlier or when human tissues stored in labs are used.

The presumption of adulthood as the criteria of the eligibility to consent can be rebutted in case of mental retardation or other conditions like, young and not matured children, patients having problems relating to learning, and patients who are not in a conscious stage, and also in cases of those admitted in intensive care units and of emergency situations. He concludes that, it is on the basis that these classes of persons are incapable of making rational decisions.

Isaiah Berlin (1969) explains the importance of personal autonomy in medical research involving human beings. He describes autonomy as, he want his life and decisions about his life to be taken by him. He doesn’t want any external forces of whatever nature to decide on his needs.

Rothman (1987) discusses about the application about the doctrine of informed consent and explains that it took many years for many medical professionals to recognize the doctrine of informed consent in its full implications. Earlier the general approach taken by the physicians as Nuremberg code is applicable to situations similar to Nazi experimentations.

Leenen (2000) reflects on the issue of consent. He opines that the consent relating to medical research has to be adequately probed and justified. It is essential to ensure the privacy of the person concerned. The research subject may be made aware that, participating in the research may not result in a disproportionate damage.
The author opines that conducting medical research is not possible with nominative data. It needs clear and accurate proposal and procedure to be followed in every stages of research. The research participant may be informed much in advance about all the process and procedure involved in a language understandable to him. It is crucial that the research participant may be made aware about the risk and benefits of the said research.

Faden RR, (1996) discusses about the secrecy maintained during the human radiation experiments by US. The author opines that the researchers were aware about the chances of severe harm to human research participants as a result of this radiation but simply ignored them. The probability of the risk factor involved in the procedures adopted as part of the research where high and can be foreseen by a reasonable professional.

Beauchamp,T.and Walters,L (1990) discusses about a reasonable criteria which may be adopted while recruiting research subjects especially from those who are not able to give an informed consent to the participation in research. There need to be transparency in the recruiting criteria especially when it deals with children or other categories of individuals who does not have the capacity to give consent.

The authors explains that, the researcher must distribute the burden of participation in medical research proportionately among the population that are well equipped and that are poorly equipped to give informed consent like, children or the mentally incompetent.

Lisa Newton (1990) condemns the emphasis on the person participating in medical research for the purpose of obtaining informed consent. She discusses that, what about the cultural and social background in which the person live in. The author points out that in certain cultural and social setup the individuals are not permitted to take the decisions affecting oneself. The right of self determination is unknown to such societal background. The right to decide about the crucial areas about the life doesn’t arise in such situation.
The author opines that it is an ethical expansionism in its most unfavourable position to speculate and conclude that the doctrine of informed consent as originated based on the moral and ethical principles accepted and practised in western countries may have a universal application.

The author concludes that the researcher need to conduct an assessment based on the cultural and social background of the particular research participant instead of applying a doctrine developed in a western setting. The magnitude of respect which an individual receives is very much based on the social and cultural environment to which he belongs.

David Wendler (2002) discuss about when researchers may obtain consent if research is done with samples taken from human body and the donor is not identifiable. He points out that there is no need to ask the consent of the source as there is no factor of risk involved. The author also discusses about when the person himself contributes body sample for research. He says the element of contribution makes the donor in the position that he cannot later claim any rights from it.

**Medico legal issues and concerns**

Johan PE Karlberg and Marjorie A Speers (2010) explains that placebo-controlled trials calculate the full medicated result of treatment, on the other hand active control trials, or dose-comparison trials, take account of the effect compared to other treatment. They also make it likely to compare between unwanted effects resulted by both the drug and underlying disease.

Placebo-controlled trials can identify therapeutic effects with a small sample size. However, it is also contested that placebos creates an artificial circumstance, showing results contrary to actual effects. It may also be considered that they give useful information and knowledge about the comparative efficiency of standard procedure.
Burtchaell (1988) opines that, when a woman takes a decision to abort, it is just giving up completely the right of trusteeship. It is from this right of trusteeship the responsibility arises. Without this right there is no chance of exercising any authority over the left over body part.

Gunter Virt (2002) discusses about the reason for exempting human embryonic stem cells and also embryonic stem cell lines from patentability. He suggests that it is mainly due to the reason that we cannot take embryonic stem cell lines without destroying an embryo.

Patent may not be granted for an unlawful act. Destroying embryo is permitted only based on the provisions mentioned specifically in the legislation. Utilization of embryo in this manner challenge and oppose the principles favouring the dignity of an embryo as a member of human race having life.

Charo (1995) opines that, the concern relating to the moral status of the embryo can be circumven totally by confronting the appropriate limits of research using embryo. He explains that these types of research need to be justified from both political and moral philosophical point of view.

Investigation in a political manner necessitate and require a change in the view point, far from the embryonic research and concentrates on an ethical stability between the priorities of those who stand against the destruction of embryo and those who favour the embryonic research and wants to take advantage of the research findings. Thus, the extreme the degree of wrong to those who oppose the weaker the chances for relaying to the political system.

Thus according to Charo’s view it is not possible to arrive at an amicable conclusion regarding the substantive conflict among the values surrounding embryo research, But taking into consideration the potential health benefits, need for such research may, outweigh the suffering undergone by the opponents of the research.

Omprakash V. Nandimath (2009) Research subject has a legal right to protect his body autonomy and self determination. This right of the research participant emergence from
Article 21 of the Indian Constitution.

Maneka Gandhi’s Case (1978) Theory of autonomy may be traced from the principle mentioned in Art. 21 of the Indian Constitution. It specifically mentions about protecting the right to life and preserving the liberty of each and every individual. The wording of Article 21 has the widest cover and implication to include a variety of rights under its heading. Any person whose rights are infringed may get the benefit of this provision.

Alasdair Maclean (2009) there is many conceptions of autonomy like, libertarian approach, liberal approach and communitarian approach. Libertarian consideration is to view autonomy generally as self determination. The liberal approach insists for including the principle of reasonableness and rationality. It needs justification based on a rational thinking for every action taken. The communitarian approach requires autonomy to have substantial moral content.

Gillon (1985) the author opines that, principle of autonomy emphasizes to treat persons as inherently valuable individuals. They possess a moral right to make decisions about their own lives.

Among the moral obligations which derive from the principle of autonomy, the most important one is the researcher’s obligation to fully inform potential research subject and respect the individual’s informed consent or informed refusal. When Autonomy is understood as self-determination it includes the individual’s capacity to think, decide and act.

Warren (1997) discusses about the legal and moral status of performing abortion. He opines that, Instrumental value of autonomy says about absolute power over one’s own body.

Richard A. Nagareda, (2008) the author discusses about the tort litigations in India. He says that in India trend of the legal system is to treat mass torts from civil liability to almost like public administration.
Singh J (1999) the author discusses about the negligence resulted during medical procedures and the need to compensate for those resultant injuries. He opines that the researcher may continue self education to improve his standard of medical care. He needs to evaluate his research subject completely and thoroughly. Maintaining contemporaneous and accurate clinical records are essential. He also needs to ensure that other professionals who assist in the care of the research subject are qualified and competent to carry out that care.

Shan D. Pattinson (2006) the research subject may often find it reluctant to litigate as establishing the requirements of negligence is very difficult in research situations. Even though the researcher clearly owes a duty of care to the participants, it is often difficult to prove that the researcher negligently designed or implemented the research protocol, or negligently failed to disclose necessary data to the participant which resulted in not doing the duty and the breach resulted in damage to the claimant.

Baker Stephen (2005) Evidential difficulties may also arise for bringing an action against an individual researcher as the decisions may be taken through a collective decision making process and the discussions relating the research protocol may have done in a very secret manner.

The firms which are conducting medical research involving human beings need to be punished if they breach the practice and procedures for experimenting new drugs in humans. Harsh punishments may be imposed, including long term imprisonment and cancellation of license.

Commercialization of medical research

Marcia Angell (2000) raises his concern that relationship between the researchers and the pharmaceutical companies is good to some extent, but an extensive relationship may hamper the benefits which the society may receive from medical research. The author argues that medical schools and institutions may prevent representatives from pharmaceutical companies from approaching young medical students.
The gifts offers by these representatives in one sense is similar as that of offering and accepting bribe. The pharmaceutical companies intend to buy the goodwill of the young professionals who in future tends to be in favour of the interest of the companies. The author concludes that the medical institutions are to provide ethical medical knowledge. They need to demonstrate that medical profession is not for sale.

David Resnik (1999) Discusses about the relevance of educating the public, researchers, law makers and other stake holders involved in medical research. He opines that all need to study from each other.

Fear and malpractices arises from ignorance. Researchers need to inform the public about new and improved methods of cure for different ailments because of medical research. The results of the research need to be published making it accessible to the general public. The public may also be given chances to express their views and impact of the said research on ethical, moral, social and cultural aspects.

The author concludes that legislation in these areas needs to be made with great caution and care. Provisions may be made in such a way to promote scientific advancement, protecting the rights of the research subject, facilitating to avoid commercialization that tends to harm the humanity through medical research.

G.Perezbustamante (1998) discusses categories that are exempted from patentability like, methods for cloning humans, procedure for altering the germ line genetic nature of humans, commercialization of embryos, any procedure which changes the genetic nature of animals, which may cause hardship and without any therapeutic advantage.

Mark Yarborough and Richard R. Sharp (2000) explain about the concerns arising as a result of media report showing monetary incentives to carry out medical research to benefit the pharmaceutical companies. This situation brings ethical issues again for debate and discussion. He opines that research institutions may put efforts to bring public confidence in them. The author explains the goals of medical research as to bring relief to ailments,
generation and progress in knowledge, protection of life, and also to guarantee the welfare of the society.

The author opines that to make these goals possible there need to be proper cooperation between the society and the research institutions. To continue the public trust and confidence in research institutions, the new researchers need to be trained and educated about the scientific, ethical, moral and legal norms which they need to follow while conducting medical research involving human beings. A responsible medical research is that in which there need to be a partnership between public and the researcher.

**Legal framework for medical research**

Greg Koski (1999) explains that the investigators are in a better position to protect the rights of the research participants than the governmental agencies. In medical research the researcher is the person who can do much harm as well as prevent harm, and do benefits to the research subjects. He concludes by saying that history reveals that sincere protection to the rights of the research participants came from well trained ethics abiding researchers and no from any government agencies.

Alexander Capron (1999) emphasis a strong independent national authority for safeguarding the rights of the research subjects constructively. He points out that the legal framework in US on this issue has not undergone much change for many years. He points out certain unchanged features of this model as wide spread authority, entrusting the responsibilities to lower authorities, taking decision based on each individual case etc.

David Resnik (2001) cautions against the move of the government to enact legislations whenever there is a controversy. Legislation without making enough groundwork, discussion and study on the reasons for the issue which causing the controversy may not render justice. He illustrates a case where the governmental restriction in the area of stem cell research leads to researchers moving to those jurisdictions which has less stringent regulatory framework. He concludes that the government may take an action with proper care and caution. A
proficient legislation may transpire from an expressive discourse with scientist in that particular field and with the opinion of the public.

Richard E. Ashcroft (2003) points out two approaches to the regulation of medical research risk like agent-oriented and process-oriented. A debate based on a moral reasoning is agent-centered, focuses on principles of duty, contact and behaviour. The debate on a proper legal framework concentrates on formulating definite standard, different methods of operation, finding out and proper regulation of organized risks.

The author describes that thinking on a moral basis, regulatory debate lawfully plays down authority which focuses on relations of humans, even when taking into account the role played by economic factors in the society. When taking a view on a regulatory viewpoint, a moral disclosure based on moral principles is uncertain, not practicable, bases on a wrong ideology which is doubtful, and not mandatory.

B. Freedman, A.Fuks, and C. Weijer (1993) Risk can be minimized by screening potential participants and by monitoring participants for adverse events during the study. Regulations relating to research of many countries always refer to minimal risk which doesn’t have greater probability and magnitude than those encountered in routine physical examinations.

Maria Freire (2001) explains that a local rule which strictly restricts research, forbid financial support, or thrust liability based on criminal proceeding for it’s perform may restrain research totally. More over that, the extraterritorial ambit of a nation whose laws fix criminal liability on issues relating to medical research consisting of human beings may also make smooth the functioning of medical research.

An organization which is not funded by the government or any other entity trying to attain shares of the market globally, invest in capital, or enlarge opportunities for research may start and continue research in a nation where there is much lesser stringent regulations to attain patent and to act upon.

Johan PE Karlberg and Marjorie A Speers (2010) explains that in every nation a new medicinal formula is developed after strict supervision and quality guarantying responsibility through various regulatory mechanisms. He enumerates the name of drug regulatory
authorities of different nation like, the Food and Drug Administration in US, the European Agency for the Evaluation of Medicinal Products in European Union, the Ministry of Health, Labor and Welfare in Japan, Health Canada in Canada, the State Food and Drug Administration in China, the Therapeutic Goods Administration in Australia, the Drugs Controller General of India in India, the National Health Sanitary Surveillance Agency in Brazil.

Morreim E. Haavi (2004) explains that the concept of negligence needs to be specified systematically for applying in medical research cases. He states the reason for reformulating the theory as the breach of fiduciary duty is substantially irrelevant in medical research. He opines that battery or trespass to individuals originated as a distinctive form of tort in medical research. The doctrine of informed consent as it applies to cases of medical malpractice may not be suitable as such for medical research cases. Substantial modifications need to be done to make it suitable for medical research involving human beings.

Prosser and Keeton (1984) elaborates the elements of negligence which the plaintiff need to establish to claim compensation like, the duty of the physician to reveal material facts to the patient, the physician failed to disclose the required information, if correct information was given regarding the procedure the consent may not have been given, the procedure conducted without properly informing the patient is the root cause of the injury and the injury which the plaintiff suffered is one of compensable in nature.

Benner (1994) Rules may be formulated in such a manner that it arises from accepted practices and customs of a particular society. A practice which is inalienable to a societal background if adopted as a rule may not be accepted and followed by the people, making the rule without any purpose. The principles like the respect for individuals, personal autonomy etc is inclusive in a rule.

William P. Cheshire (2001) says that, sacred approach always compliments the embryo as the biological creation of a new human life. It identifies the embryo’s status among the
human family. It acknowledges the status of the embryo as a living organism of the species ‘Homosapiens’.

It envisages human dignity and sanctity about human life in its continuous process, during all stages of its development. It specifies that all human life is created accordance with a good amount of human dignity. Sacred approach believes that embryonic life has amazing potential.

Ford J, Reuter (1990) considers that, the Declaration of Helsinki reflects the conflicts to preserve and protect human rights of the research subjects and the generation of knowledge. Both are very much essential for the welfare of human beings. There need to be a proper balancing of the rights of the research participants and the effort to advance scientific knowledge. One cannot be sacrificed on the cost of another.

Vanderpool (1996) The principle of respect for persons would consider persons not merely as isolated individuals, who consent or refuse to consent to participate in research, but also as members of communities. Right of one individual in a community very much depends on the rights and duties of other individuals in the community. An individual cannot be seen as an isolated from the rest in the society.

Edmund D. Pellegrino and David C. Thomasma, (1993) opines that Medicine, as a human activity, is of necessity a form of beneficence. The characteristic feature of these regulations that stipulate this principle consider not cause any injury and tries to increase the advantages and reduce disadvantages. The duty of beneficence creates an obligation to provide a positive benefit to the research subject.

Dix Andrew (1996) opines that the requirements for valid patient consent involve meeting certain conditions like, the consent must be freely and voluntarily given, it must cover the process to be conducted. The consent may be given after having full information about the procedure. The consent must be given by the person who is competent of consenting.

Fleming (1992) The tort of battery derives from the right of an individual to autonomously dictate what is done to her body. It provide a remedy for a form of trespass that result from intentionally causing harmful contact with another. It aims for two fold purpose, like affording protection to the individual not only against bodily harm but also against any interference with his person which is offensive to a reasonable sense of honour and dignity.
Richard R Love and Norman C. Fosst (1997) The notion of informed consent varies with the custom and practices of each country. ICMR has set guidelines for community consent in cases in which research necessitate treating any group, person or community as a participant of experimentation. It mentions about the principle of voluntariness and informed consent. It may be made applicable to the society as a whole and to each person who is involved in the medical research.

Kennedy and Grubb (1994) see the concept of competency and understanding in this way. Does a test which stipulates that the research subject understands means that the doctor must satisfy himself: that the patient does in fact understand what is involved, or that the patient is capable generally of understanding though, as it may subsequently transpire, he did not understand in the particular case, or that the patient as a reasonable patient is capable of understanding or would have understood.

Lisa Day (2002) Basis of adherence to the ethical principles is the moral responsibility of each researcher. The stages of autonomy of those research participants who are not competent are respected by asking the guardian or parent to give surrogate consent for that individual participant. Asking for proxy consent or surrogate consent is way through which health care gives due predominance to dignity and respect to each individual for protecting autonomy.

Eckstein (2001) A legal structure need to be formulated to ascertain the ramifications to the field of medical experimentation involving children which is definitely a complex job. It involves three important approaches of law that pertinent in experimentation consisting of minors like:

1. Responsibility of the parent,
2. Judicial authority to intervene in such issues and
3. The rights of the child.