Chapter- 2

Experimentation on Human Beings: Ethical Concerns

2.1. Introduction

The history of biomedical science has proved that the experimentation on human beings is an essential part for the development of medical sciences. The present status of biomedical sciences has been possible only because of the involvement of human beings in various investigative experimentations performed in different phases of human civilizations. Scientific communities have realized that biomedical sciences would come to a halt without experimentations on human beings. However, scientific necessity is not the sufficient ground to justify for human beings' involvement in research. Now-a-day, the investigators have to face lots of challenges concerning human values, while making use of human beings in biomedical experimentations. They have to justify that using human beings for experimentations would not violate the dignity and the sanctity of the subjects involved. Thus, the issue of human subjects in experimentations has become a sensitive one from ethical point of view.

It is important to note here that until the middle of the 19th century the issues regarding the use of human beings in biomedical experimentations were not so sensitive. It was because of the lack of awareness and the low demand for human beings' involvement in experimentations. But, towards the end of the 19th century, human being's involvements have increased tremendously. Consequently the awareness about the debatable issues regarding the value of human life reaches the apex level. It is also

interesting to note that most of the major discoveries of biomedical sciences have come out during late 19th and 20th centuries. Talking about the history of experimentation Hans Jonas has made an interesting remark-

> Experimentation was originally sanctioned by natural sciences. There it is performed on inanimate objects, and this raises no moral problems. But as soon as animate, feeling beings become the subjects of experiment, as they do in the life sciences and especially in medical research, this innocence of the search for knowledge is lost and the questions of conscience arise.[1]

Jonas points out that the questions of moral issues arise mainly because of the use of sentient beings. However, though most of these concerns are related to the research on human beings as well as non-human beings, their depth and intricacies seem to differ a lot.

Research concerning human beings can be categorized as therapeutic and non-therapeutic.[2]The subjects involved are themselves patients in therapeutic research. This type of research was the dominant method in medical sciences until well into the present century. Today the increasing demand for human beings' involvement in medical research has changed the picture of medical experimentation. It involves the designing of procedures that systematically manipulates subjects and the use of controls for the purpose of gaining knowledge. In non-therapeutic research the involving subjects are not patients. They are involved only to gather the scientific knowledge and to develop the biomedical sciences. Moral concerns arise when research subjects are involved forcefully or unknowingly in experimentations. Such kind of imposing horror on human beings arises when common good takes more priority than individual good. Throughout the

course of medical history plenty of cases are found on record where human subjects were forcefully engaged in experimentation to satisfy the thirst for knowledge. For the enhancement of medical sciences the employment of properly controlled clinical trials has been of vital importance now-a-days. This form of experimentation has been generating some difficult and perplexing moral issues. Some of the issues are like the question of sanctity of life, objectification and instrumentalization of the involving subjects, and denial of autonomy. The main purpose of this chapter is to deal with the systematic analysis of these pertinent ethical issues and to explore the ensuring conditions under which the study participants are protected, and ultimately research is conducted in a way that serves the needs of such participants and of the society as a whole.

2.2. Historical background of human experimentation

Experimentation involving human beings has a very contentious history. The scientific community learnt to use living creatures in research as early as 5000 years back. Ancient Egypt, which is the first civilization with written records, shows the extensive interest in medicine. Like all of the early civilizations, such as the Mesopotamia and the Sumerian civilization, Egyptian biological science was also essentially empirical and pragmatic with little interest in theory.[3] Fortunately or unfortunately, the medical science has come to its present status only because of the effective use of human and non-human beings in the investigative experimentations performed in different civilizations. The historical evidences have proved how much important the involvement of human beings in experimental processes for the development of biomedical sciences has been. On the other hand, the evidences also point out how moral issues have been seriously neglected throughout the biomedical history. So, to have a detail and clear understanding of the

continuity of violation of ethical principles or rules, historical analysis is very significant. It will also help us to meet the present demand of ethical framework to regulate the experimentation processes.

Research involving human beings have been fraught with controversies from its very beginning. During the ancient period arguments for and against involving human beings in experimentations were also heated. Though, it has no definite and contemporary records to verify, yet, it can be assumed faintly from *De medicina*, of the Roman historian Celsus.[4] Despite the controversies, the cases of experimentation on living human beings began in Hellenistic Alexandria (300-200 BC).[5] At that time, the condemned were forcibly used in deadly experiments that might lead to death. It was the first golden age of anatomy, when dissection and vivisection of human bodies began and developed simultaneously. Here, the condemned signifies the criminals and political prisoners who were ranked with animals in the social order. Both dissection and vivisection were the methods to understand about physiology of our body. Dissection shows the essential structures of our body and vivisection reveals the functioning of these structures. The pioneering Alexandrians were probably influenced by contact with ancient Egypt. The best of Alexandrian biology is exemplified by the outstanding achievements of the two scientists, who have performed human vivisection on a scale unmatched in human history. They were Herophillus, the father of anatomy, and Erasistrtus, the father of physiology.

The continuity of dissection and vivisection was broken after the fall of the Roman Empire in 5th Century. Almost for 1000 years (5th- 14th Century) human dissection was discouraged and dogmas instead of observation and reason were accepted

as the only valid source of true knowledge. This is the period of middle age when all that had been known in science was lost and no new discoveries were made.[6] But, the period of Renaissance (14th- 16th century) had fostered the reappearance of science and particularly the vivisection.[7] It was the new birth of science which in essence was a revolt against dogmas. Renaissance scholars sought truth through observation and reason. They discarded authoritarian scholasticism. For them argument and logic were the sole and sufficient manifesto to explain how nature is composed. "Do not tell me, but show me" was their slogan. The basic premise was: A proposed function, if true, will result in a certain consequence, which is tested by experimental demonstration. This new method of experimental manipulation was the breakthrough to modern sciences. It is exemplified in the discovery of the circulation of the blood. During this period also human beings were used in experimentation against their wishes. It can be compared to the atrocities of Alexandria.

The philosophical mood of the 18th century Enlightenment was also optimism.[8] Interestingly, in this period certain experiments occurred where innocent human beings were used.[9] John Hunter (1728-1793) was one of the most influential medical practitioners of the late 18th century.[10] He has been called 'the Shakespeare of Medicine.' He was a famous and a skillful anatomist. He made important advances in vascular surgery. He was curious about the power of generating heat that was peculiar to animals while they were alive. He designed his thermometer and took temperatures of live animals and humans subjected to extreme cold. He found that they had power whereby they are capable of resisting any external cold while alive, by generating within them a degree of heat sufficient to counteract it.

It is evident that science has been able to provide more and more accurate and truthful descriptions of nature and its functioning since the 17th Century. Well into the 18th century, many scientists believed, or at least asserted, that they were moved to reveal God's great design in nature to show the beautiful intricacy of the universal harmony. But, in the 19th century science, God was dropped. During this period science was transformed as a serious and respectable profession. The scientists were able to provide empirical, rational, and testable explanations of the universe, which became increasingly correct as new discoveries were made. For the researcher, it was a source of intellectual pleasure. It is to be noted here that from the period of mid- 19th century, the involvement of human as a subject in experimentation becomes an indispensible one for the progress of science, for the improvement of clinical practices and for modern medicine. Examples from the 19th century would not be complete without reference to the experiments involving black slaves in the United States.[11] During the period of 20th Century, some of the investigators in their experimentations taught us a moral course of actions, subsequently it helps to formulate the ethical guidelines for human subject experimentations. One historic example of this period was Walter Reed and Yellow Fever Experiments.[12] There are some unusual features of this experimentation. Firstly the introduction of a written document that outlined the risks involved in the efforts to transmit yellow fever and exposed the reality that there was no effective treatment for the disease. Secondly, Reed and his colleagues have commitment to be first human subjects in critical clinical trials. It was an unforgettable experiment in medical history. Walter Reed has given a moral lesson to the physician investigators, because of which *Walter*

Reed Society was formed in 1950 in memory of Walter Reed's contributions in order to respect him not just a successful researcher, but as a self-sacrificing researcher.

Another historic example is the Nazi human experimentation. In this experimentation, a large number of people were involved, which was actually conducted in the concentration camps by the Nazi forces during World War II.[13] The aim of this experimentation was to help German military personals to deal with the injury situations of their military fellows in combats. The Nazi government imposed no mandatory professional standards on conducting of experiments. During that time no international humanitarian or medical agency intervened to protect the victims. Human bodies were manipulated unnaturally, and bodies, body parts and internal organ were exploited in this experimentation. Thus, Nazi investigators opened the floodgates to successive waves of immoral experimentation and research abuses. Around 1500 inmates were selected for their experimentation. It was believed that the changing standards of medical ethics and research practices early in the 20th century paved the way for the Nazi medical atrocities. Whatever the cause of their atrocities, both the Nazi medical experiment and the Second World War had removed the civil rights and humane ethics. Apart from these, the Mustard Gas Test**,** the Tuskegee Syphilis Experiments, the Jewish Chronic Disease Hospital Case and the Hepatitis Experiments at the Willowbrook State School[14] are some of the most inhumane historic biomedical experimentations on human beings.

It would be noteworthy to mention here that from the middle of 19th century the demand for the use of human subject has increased tremendously in medical sciences. This is because of the new and critical situations faced by the medical sciences. Physicians have been paying their attention to the emergence of benefits to man entailed

by the application of the experimental method and the implementation of innovations into practice. Well-being of the individuals was their main aim at the initial stage. But, gradually their attention turned to the advancement of scientific knowledge. As a result, a clear picture of transition from valuing the good of the individual to a concern for the common good has been seen from the mid-19th century. But, after the 2nd World War, as a reaction to imposing horrors on human individuals in the name of common good, attention was paid to the reassessment of the risks and benefits of experimentation and of regulation of its practices. This attitude is sustained till today with some changes. Here, we have seen the increase numbers of ethical norms and bioethical institutions that asses the ethical legitimacy of projects and safeguard the interests of the subjects of experimentation. To prevent the violation of human dignity and to respect the primacy of the individual and the individual good over common good various attempts have been made from the very beginning of the post World War-II. Consequently, various codes, declarations and ethical guiding principles have been formed at National and International level to regulate smoothly the biomedical research involving human beings.[15]

2.3. Types of experimentation

As found in the literature of biomedical experimentations, there are two prominent types of experimentations involving human beings. One is therapeutic and another is known as non-therapeutic experimentation. Both are also known as clinical and non-clinical research respectively. In therapeutic research, the physicians are free to use new diagnostic and therapeutic measure, if his or her judgments offer a new hope of saving life, and alleviating pain of the subject involved. In this type of research, the potential

benefits, hazards and discomfort of a new diagnostic method is being measured in comparison with the advantages of the best current diagnostic and therapeutic method. Therapeutic research is ethically justifiable on the basis of its potential diagnostic or therapeutic value for the patient.

On the other hand, in non-therapeutic research the involving subjects are the volunteers- either healthy persons or patients for whom the experimental design is not related to the patient's illness. It is purely the scientific application of medical research on human beings. Here, the physicians have strong obligations to protect the life and health of the involved subject. In non-clinical research, the investigators and their teams have the duty to discontinue their research at any moment, if they are convinced that it may be harmful to the involved subjects if their research is being continued. Here, the interest of science and society should never take precedence over the considerations related to the well-being of the subject involved.

2.4. Importance of human experimentation

Experimentation is a scientific procedure, which is applied to discover new things, to test a theory or to demonstrate a fact. It refers to a class of scientific activities designed to develop or contribute to knowledge. The investigator controls the setting of the experiment in order to report firmly for all the factors at play and to be reasonably certain of what cause in experiment led to what effect.[16] Reflecting upon the importance of experimentation in biomedical sciences, it can be argued that medicine is inherently experimental. Even the most widely accepted treatment need to be monitored and evaluated to determine whether they are effective for specific patients and for patients in

general. It is because every patient is different and what is an effective treatment for 90% of the population may not work for the other 10%.

2.4.1. Why experiments?

Throughout history, it is evident that biomedical sciences cannot go ahead without observations and experimentations. In biomedical sciences, experimentation is essential on both human and non-human beings. Advancement of scientific knowledge in biomedical sciences would come to a close if human subject's involvement in research activity were not entertained. The French Psychologist Claude Bernard has declared that 'it is our duty and right to experiment on man, whenever it can save his life, cure him or gain him some personal benefit.'[17] It clears that human beings' involvement is very significant in bio-medical sciences. It is significant in both the therapeutic and non-therapeutic types of research. Throughout the middle of the 19th century the demand for human subject's involvement in medical research (both in clinical and non-clinical sense) has increased tremendously due to the new and critical situations faced by the medical sciences.

2.4.2. Benefits towards humanity

At the most basic level medical research aims at learning what causes disease and how they spread. Once it knows how diseases are caused and spread, it can work out ways to prevent them. It is a fact that preventative medicine is one of the most important developments in the history of medicine. Diseases that were once common are now very rare. Not only can medical research prevent illness, it can also cure it. Medical research requires an understanding of the basic medical sciences and a great deal of testing to

ensure that the treatments work the way that they are supposed to. Once a treatment has been developed, it is important to determine the way it is supposed to work satisfactorily and is safe. This has caused the birth of another branch of medical research called clinical trials, where the researchers will test the medicine or procedure on people who have the illness that is being tried to be cured, and keep track of the results. These trials will establish how effective the medication is and whether or not it is safe for widespread use. These trials are important for making sure that people are not given medications that don't work or are not safe.

Clinical research is conducted at a variety of sites and by a variety of bodies. Academic health centers, government labs and clinics, community hospitals, state health organizations, and managed care and pharmaceutical industry sites are all active participants in the nation's clinical research enterprise that is necessarily multidisciplinary. The success of clinical research depends on funding from both federal and private sector sources. Clinical research has changed the face of modern medicine. Fifty years ago, at the end of World War-II, physicians had little ability to effectively treat or prevent any of the deadliest diseases. Most of the staples of modern medicine we enjoy today were unknown. Some of them are- antibiotics, vaccines for polio and several other severe infections, most hormone replacements and steroid therapy, effective drug therapies for cancer and psychotic illness, feasting for genetic disorders, coronary bypass surgery, transplanted organs and artificial joint. These and other successes have encouraged public eagerness for research involving human being and belief in the potency of modern medicine.

Biomedical experimentation involves doing research on public health, bio-chemistry, clinical research, microbiology, physiology, oncology, surgery and research on many other non-communicable diseases such as diabetes and cardiovascular diseases. In all these areas, the importance of human being's involvement is undeniable. The credits obviously will go to the continuous processes of observations and experimentations in biomedical research due to which the longevity of humans over the past century has increased significantly. Some of the major benefits of bio-medical research are- the vaccines for measles and polio, insulin treatment for diabetes, classes of antibiotics for testing a host of maladies, medication for high blood pressure, improved treatment for Aids, and increasingly successful treatments for cancer etc. Many challenges however remain, including the appearance of antibiotic resistance and the obesity epidemic that entails the continuous process of bio-medical research. Apart from this there are still many unanswered questions about the functioning of the human body, the causes of disease (both familiar and novel) and the best ways to prevent and cure them. Medical research involving human beings is the only means of answering these questions.

It is a common belief that any ill patient wants to be cured completely as early as possible with no side effects. Accordingly, it should be the duty of every doctor to provide effective treatment to his patient. The ideas that complete cures are a delusion has never been accepted by some doctors, since they believe that it would stop us to look forward. Of course, there may not be many complete cures, but there are treatments for numerous conditions that previously would have killed someone or disabled for life. All these would not have been possible had research not been undertaken in medicine. So,

medical research involving human beings has a great importance. The ultimate goal of medical research is complete cure. It requires sacrifice on the part of both patients and doctors.[18] In the literature of bio-medical ethics, philosophers have given their views regarding the moral justifications of involvement of human beings in research activity. With their views, they have encouraged the human being's involvement in bio-medical research. However, they are emphatic in their arguments on such kind of research where the rights and welfare of human participants are being protected.

According to Leon Eisenberg, the principles of beneficence and justice can reasonably justify the involvement of human subject in medical experimentation.[19] Latter these two principles were included within the guiding principles of the U S National Commission for Protection of Human Subjects in Biomedical and Behavioral Research (1979) in the Belmont Report.[20] However, Hans Jonas vigorously challenges both approaches of Eisenberg regarding moral justification of human subjects' involvement in biomedical research.[21]Jonas asserts that the utilitarian principle of maximizing overall social good could not lead us to permit experiment, because it violates other important values, such as the principle of individual dignity and distributive justice. Jonas reminds us forcefully that medical ethics is not an ethics of maximizing benefits and minimizing harm. For him, voluntary involvement of human subjects in research should not be sought or accepted unless the community is faced with the sort of clear and present danger. Jonas's view is that, medical experimentation with human subject is necessary for the advancement of scientific knowledge, and the advancement of scientific knowledge is necessary for the promotion of public health. Thus, for the promotion of public health or in short, in favor of societal interest medical experimentation with human subject is

necessary. Here, no one should ignore the principle of the sanctity of human life, i.e. according to Jonas, when research is conducted with human beings one ought to assign a much higher priority to the value of minimizing the risk of harm to research subject than to the value of advancing scientific knowledge. Thus in Jonas' position, protection of rights, dignity, and inviolability of the individuals are supremely important. In Kantian terms, he objects to the use of a person as a means to an end. And because of this primary commitment, Jonas is unwilling to accept either ordinary social benefits or the notion of universal duties to society as sufficient justification for human research. Criticizing Jonas' view, Arthur Schafer points out that since virtually every medical procedure involves some element of risk (for example, even the taking of a blood sample carries a slight risk of infection), it may not be often morally proper to ask individuals to volunteer for biomedical experimentation. According to Schafer, only a transcendent social sanction can justify human experimentation. Mere benefit, however great, is not enough for him. The principle of individual's dignity must remain inviolable while experimenting with human beings. Bernard Towers, has also pointed out the importance of medical experimentation with human subject for the advancement of scientific knowledge. But, he clearly mentioned some safeguards such as informed consent of the participant to ensure that no exploitation would occur.

The above arguments regarding justifications of human beings' involvement in biomedical research have clearly pointed out that a research project that has no social value or is not scientifically valid is exploiting the research participants, because they are being 'used' for no good end. Similar things can be said about research that involves unfair participant selection or that does not have a favorable risk-benefit ratio. There are

three basic areas on which the ethics of a research project will hinge. Whether any given research project is ethical or not, we need to be able to analyze it by reference to these concerns.[22] These areas are: firstly, what is necessary or valuable research, in terms both of its goals and of whether its methods will achieve that goal reliably; secondly, the doctor's moral obligation to do the best for her patients; thirdly, considering the wishes and needs of patients and potential research participants, who have rationality to be respected and benefits to gain or lose by virtue of their participation in research, about which only they may know.

Thus, the obligations of society as well as the obligation to protect its members from harm and to secure the conditions of its preservation are essential for the justification of any biomedical research involving human beings. Jonas has put the nature of this obligation very clearly in his article, entitled, '*Philosophical reflections on experimenting with human subjects'*. In the ethical justification of any particular research project the first consideration is an appraisal of the value and validity of the anticipated consequences. The scientific design of the research proposal must be adequate; otherwise one cannot predict accurate results. Inaccurate results are of no value to society. Moreover, the anticipated results must be of sufficient value to justify the exposure of human subjects to the risks of harm presented by the project. These are all beneficence-related requirements. Apart from these, the ethical justification of a particular biomedical project requires responsiveness to rules or norms related to the ethical principles of respect for persons and justice. It has been found, in Guideline-1 of *the International Ethical Guidelines for Biomedical Research Involving Human Subjects*, promulgated by the Council for International Organizations of Medical Sciences (CIOMS) that-

> The ethical justification of biomedical research involving human subjects is the prospect of discovering new ways of benefiting people's health. Such research can be ethically justifiable only if it is carried out in ways that respect and protect and are fair to the subjects of that research and are morally acceptable within the communities in which the research is carried out. Moreover, because scientifically invalid research is unethical, in that case it exposes research subjects to risks without possible benefit. Investigators and sponsors must ensure that proposed studies involving human subjects conform to generally accept scientific principles and are based on adequate knowledge of the pertinent scientific literature.[23]

Biomedical research cannot be self justificatory as pure mathematics that engages with abstract problems. It must answer the question: why this study? This question itself has two distinct (though related) elements: technical and ethical. The recognition of the ethical aspects, which is as relevant as the technical aspect, is the basis of the growth of the field of medical ethics.[24] In narrow historical sense medical ethics refers to a group of guidelines, such as the oath of Hippocrates, generally written by physicians, about the physician's ideal relationship with his peers and patients. But, in modern sense it refers to the application of general and fundamental ethical principles to clinical practices. Recently, the term has been modified to 'Bio-medical ethics'. It was fashioned in 1970 by a biological scientist, Van Rensselaer Potter. According to *the Encyclopedia of Bioethics,* it is the study of the ethical dimensions of medicine and the biological sciences.[25] Bio-medical ethics devotes itself mainly to the systematic analysis of different moral issues relating to the life and death questions. Their objective is to ensure that the involving subjects are protected and ultimately experimentation is conducted in a way that provides the needs of participants and of society as a whole.[26]

2.4.3. Contemporary research

Recent interests of the biomedical scientists are mainly on embryonic stem cell research, research on human embryos, genetic research etc. Stem cell research is very important for the advancement of tissue therapy as well as organ replacement. It is to be noted here that stem cells may be obtained either from very young human embryos or from certain tissues in adults. Similarly, fetal research is useful for the development of vaccine. It involves fetal cells and tissues, which are obtained from voluntary abortions. Another important area of bio-medical research in contemporary period is genetic research. In order to increase the information about specific individuals, genetic research is very significant. In all these area of research, human beings are used as subjects for the development of biomedical sciences.

2.5. Moral issues concerning human experimentation

The debatable issue that is raised in bioethics today is how far the human being's involvement in medical research is justifiable. From the time of Alexandria, arguments both for and against have been raised regarding the involvement of human beings in experimentations. However, after the World War II, the horrors performed by Nazi physicians in concentration camps revealed and reminded us how far uncontrolled experimentation could go. Consequently, *the Nuremberg Code* (1947) drew up, which was widely acknowledged as the epitome of the ethics of experimentations with humans.

In many cases of biomedical research, the human subjects even did not know properly that they were participants in research activity. For example, the clinical study that was carried out for decades in Tuskegee, Alabama between 1932 and 1972. Most of

the times the risk factors related to experimentation have been never explained adequately to the subjects involved. There is a prevalent belief behind this fact, that is, if the attention is paid to the matters related to the involved subject of experimentations, such as, the risk factors, subject's autonomy, informed consent etc. then nobody would come to participate in the experimentation as a subject and as a consequence this would '*block progress'*. But the fact is that science is not the highest value to which all other values should be subordinated. So, the question of the legitimacy of experimentations with human subjects is still an open one.

It is to be noted here that the increasing demand for human beings' involvement in biomedical research since the middle of the 19th century has been posing lots of sensitive moral issues and dilemmas. As a result, justification of human being's involvement has become a challenging issue. While considering the moral justification for a biomedical research involving human being the issues that need to be considered seriously are: social value, scientific validity, fair participant selection, favorable risk-benefit ratio and respect for human research participants. It is to be noted here that all these issues are based on a more general principle of minimized exploitation, which is the fundamental challenge of all research involving human beings. The four colonial principles (non-malfeasance, beneficence, respect for person, and justice) are also based on it, though they do not invoke the language of exploitation. As Jonas has rightly pointed out, moral issues arise when any sentient beings become the subject of experimentations. The questions of dignity and sanctity of life are necessarily attached with any biomedical research involving sentient beings. However, the proper justification for human beings' involvement in biomedical research depends on the adequate response

towards these moral issues. The questions of sanctity of life, the questions objectification, the questions of instrumentality, and the questions of denial of autonomy,[27] are some of the pertinent moral issues that have been discussed in this chapter.

2.5.1. Sanctity of life

The 'sanctity of life' is a phrase that is generally used to understand the intrinsic value of life. It is a moral assurance about how living beings are to be perceived and treated. Belief in the sanctity of life prescribes a certain way of looking at the world. Rightly understood, the sanctity of life is such a moral principle which implies our moral obligations to all living beings. Ethicists have claimed that by retaining the sanctity of life principle, one can reasonably justify the involvement of human beings in experimentations because it can protect the dignity and worthy of a human being. Throughout the biomedical history, it is evident that in most of the biomedical research the sanctity of human life becomes ridiculous. The sanctity of human life today also has been mocked and messed up by biomedical scientists and researchers due to their quest for something new to solve problems.[28]

Sanctity of life is such a principle that can help us to understand to some extent why killing or harming is wrong independent of its other impacts. Someone who believes the holiness, the sacredness and the purity of life must hold that taking a life or harming someone is directly wrong. Here the wrongness of killing or harming is independent of its impacts on other people. It raises one crucial problem that is- what counts 'life' here? Temporarily it is pertinent to avoid this difficulty here by stating this principle in term of human life. If we have become clear about the reasons why killing or harming a man is

wrong, then it will help us to better understand whether the same reasons should make us to respect animal's or plant's life as well.

Let us start with the principle that taking human life is intrinsically wrong. The concept of human life that is implicit in taking a life itself is not very clear because it raises some important boundary problems. These problems need a very careful discussion. When does the life of human being begin? Is an eight-month fetus already a human being before his birth? How about a newly fertilized egg? Taking life or killing a human is intrinsically wrong. Those who believe this may also say that being alive is in itself intrinsically valuable. If being alive is intrinsically valuable then it may be an argument for the sanctity of life. Because sanctity of life simply asserts that there is a value of life to be alive. It also takes away the views of taking life at any circumstances. Killing is wrong, most people believe it. But why killing is wrong? The answer is not a straight one. There are some people who firmly believe that killing is not wrong in all circumstances. They believe that there are some circumstances where killing is justifiable. The reason is avoidance of a greater evil. For example, in the case of war where the defense of a class or of a state is involved, killing of the opponent is legally justifiable. If this view is right then it is also not wrong to harm or kill human life in the name of medical research. But, sanctity of human life principle never allows harming or killing human beings in the name of medical research. This principle firmly asserts that each human life is sacred. So, it is our moral responsibility to respect and honor each human being's life equally. This principle also asserts that the value of human life is not based on quality of the life but on the sacredness of the life. It clearly points out that the being alive is the criterion for human beings to be honored and respected. But in the

biomedical research, this value of being alive is often neglected in the name of medical enhancement. The investigators or physicians often emphasize the centrality of the illness of the patient rather than the patient himself and thus neglect the human values. These problems have arisen in some cases, as a result of free enquiry, which permits scientists to carry out scientific inquiry into all spheres of human life. The scientists have argued that science would not have achieved so much for comfort and utility of man, if they were not allowed free enquiry. But, free inquiry should not be regarded as a freedom that has no control. So the medical research must be controlled by strict moral as well as legal laws, so that the sanctity of life is being secured. Most of the developed countries have formulated certain laws to supervise the biomedical research in their country. But in many other countries, the government still has no control over the biomedical experimentations. The life of human beings is sacred, and sanctity of life simply demands its preference irrespective of how worthless it may look like in the eyes of people.

However, there are some cases which may be cited against the above view that being alive is intrinsically valuable. These cases take the side of the view that taking life is better than leaving alive. For example, there are some people who are suffering from deadly diseases and in great pain without any hope of cure. Might such people not be better off if dead? Without giving up the view that life is intrinsically valuable this question can be considered. A man is unconscious yet his life is valuable, since being alive is intrinsically valuable. There is no way of disproving this. But in case of a life in permanent coma, is it preferable to die than being alive? From the subjective point of view, there is nothing to choose between life and death in this case. But, John Harris in his work *The Value of Life* has shifted the issue of sanctity of human life to the value of

moral life.[29] For him, what we need to know is not when life begins, but rather when life begins to matter morally. From this point of view, fetus is not morally valuable and so could be eliminated by its mother. Similarly, the correlated question is not when does life end? But rather, when does life cease to matter morally? It clears that the incurably sick person as one who has lost the moral life that matters most and so should not be allowed to continue to be a waste pipe draining the resources of others, who are 'the valuable ones.' Kant also points out that when someone is losing his previous dignity by suffering and sickness, we should help him by death. But, opponents, like Philllpa Foot, have argued that taking life is not permissible, for whatever reasons, without his proper consent.

People, who believe that killing is wrong, independent of its impacts on other factors, regard life as the final good. But what happens in the case of permanently comatose existence of a person? Such a person's life is almost indistinguishable from death. Are the persons who are in comatose not valuable? The belief in the sanctity of life claims that being alive has only instrumental value and what is intrinsically valuable is nothing but consciousness. Why consciousness is intrinsically valuable? Someone may say that it is necessary for giving us happiness. Consciousness means simply awareness or having experience of what is going on around us. For being consciousness a person needs to be alive, so being alive is valuable, but it has only instrumental value. For consciousness being alive is necessary, but simply being alive does not mean that he is being conscious. So, consciousness has a greater value than being alive.

Before going to evaluate the belief that consciousness is intrinsically valuable, it is pertinent here to discuss about the various kinds of consciousness. There are two main

kinds of consciousness — 1) Mere consciousness, 2) High level consciousness. Mere consciousness means simply awareness or having of experiences. But the meaning of mere consciousness is different from the metaphorical use of the high level of consciousness. Jonathan Glover assumes that being conscious is intrinsically good, and it is nothing but mere consciousness, rather than a high level of consciousness.[30] His suggestion is that, there is one universe, and containing consciousness and being a member of this universe is intrinsically valuable and also better than others which do not have. There is another problem that often face if it has accepted the claim that it is directly wrong to take human life because of the intrinsic value of mere consciousness. The problem is concerning animals. We often give a special value to human life as against animals' life. But animals or at least the higher ones seem no less aware of their surroundings than human beings. Why we do give preferences to human beings, though animals have consciousness? An example may clear the fact here: suppose there is a flood and I am faced with the choice of either saving a man's life or saving the life of a cow. Here, if all the side effects are left out of account, failure to save the man seems worse than failure to save the cow. The person, who believes that the sanctity of life rests solely on the value of mere consciousness, is faced with a dilemma. Either he must accept that the life of the cow and the life of man are in themselves of equal value or he must give reasons for thinking that cows are less conscious. There is no doubt that human beings have some abilities that animal does not have, such as the abilities to speak or to do highly abstract reasoning. But simply by virtue of these abilities it cannot say that people alone are conscious. There are lots of examples, in which both human beings and animals respond similarly to their surroundings. Again there is no neurophysiologic

evidence that suggests humans alone can have experiences. In the next chapter, the issues of animals have been discussed in detail, with a view that all sentient beings have their right to live.

2.5.2. Objectification

Objectification usually refers to the transformation of human beings into objects of medical manipulation. In medicine, it denotes the primacy of the body or bodily states and measures over any other subjectivity. Objectification also signifies dehumanization because it involves a professional neutralization of (patient) agency.[31]While the value or goal of a research project is considered to be prior, the issue of objectification of involved subject has the possibility to rise. It is a challenging moral issue that needs to be considered, so far as research involving human subject is concerned. It is against subjectivity and treats human as an object. Individual autonomy has no place here. In biomedical research the issue of objectification is raised when societal benefits take top most priorities by ignoring the individual autonomy. Most of times, the involving subjects are intentionally used in non-therapeutic research for gaining knowledge. If the matter is considered from absolute sense, then it is not justifiable from ethical point of view. Different codes and rules are formed at national and international levels to protect the dignity and autonomy of research subjects, so that they cannot be used as an object in any biomedical research. In therapeutic research the involved subject itself is a patient therefore the question of objectification is not directly raised here. But, in the non-therapeutic research the question of objectification of the involved subject is raised. In non-therapeutic research the involved subject is a healthy human being. He has participated in the research process only for the development of medical sciences, which

has tremendous societal value so far as public health issues are concerned. How much importance to individual's autonomy, their values of life has been given while experimentation with human subject in non-therapeutic research? The investigators have an obligation towards the involved subject, not to use as a means even for the noblest purpose, since it will violate the dignity of human being. Here, the problem of conflict between purpose and obligation, the common good and the individual good, and the public welfare and private welfare does rise. Can both the purpose and the obligation be satisfied? If not, what would be a just compromise? Can it be said that the needs, interest and rights of society are as clear and distinct as the needs, interest and rights of an individual? Societal needs are abstract and most of the time they are subject to our definition. So, there is always an ambiguity when we define such concepts as societal good, public welfare etc. The individual needs are concrete and these are prior to all definitions, its basic goods are more or less knowable facts.[32] Is it mandatory that individual good must be sacrificed for the societal good or public welfare? From the point of view of utilitarianism, this kind of sacrifice may be desirable, since maximization of happiness or good is the sole aim of this theory. For example, at the Nuremberg Trials (1947), the Nazi doctors used utilitarian arguments to justify their experiments. The Nazi doctors perhaps did not try to show that what they had done to their experimental subjects was intrinsically good, but rather they tried to show that under the circumstances, their research had to happen, because the consequences of it not happening were much worse. We can take another example here to simplify the situation. Suppose someone decides to have an abortion. No one would argue that to have an abortion is in and of itself a good action. It could only be found 'Good' in the sense that, in that person's mind anyway, not

to have an abortion would lead to worse consequences than having an abortion.[33] Thus the utilitarian must always be justified in doing the least bad things which is necessary to prevent the worst thing that would otherwise happen in the circumstances.

But, Hans Jonas has clearly mentioned that utilitarian ethics is inadequate to deal with the ethics of human experimentation. Of course he has mentioned that 'extraordinary danger excuses the extraordinary causes'. It implies that Jonas has allowed 'the submission of human subject in research which is hazardous if and only if the community is faced with a sort of clear and present danger.' Another important question arises here: who will come voluntarily to submit himself? 'Since virtually every medical procedure involves some element of risk (for example, even the taking of a blood sample carries a slight risk of infections).[34] So, is it morally proper to ask individual for medical experimentations? We can take here the example of organ transplantation research to clear the ethical problems of research goals involving human beings.

In the case of organ donation from dead bodies there are two areas of concern: firstly, the respect that is owed to the dead. It might seem absurd to think in terms of harm when removing organs from a dead body, but certain other practices raise questions about it. Respecting the physical remains is a way of showing respect for the person whose body it was. It must remain at least a concern that transplant surgeons have to harvest organs from bodies for therapeutic purposes. The public disturbance caused when it becomes widely known that organs and other body parts have been taken without permission is evocative of concern and sensitivity of the issue. Secondly, the shortage of organ donation is another area of concern. As the techniques for organ transplantation are refined and the number of patients who qualify for organ transplantation increases, so the

waiting lists for donors grow longer. Most of the time, the availability of organs is based on chance. But, is it fair chance and are children given high priority? Similarly, regarding the condition of donor organs, the organs need to be in a healthy condition. From the moment blood ceases to circulate in an organ it began to deteriorate rapidly. If a brain dead patient is kept on life support, then the organs remain vascularized as the blood continues to circulate around her body. It effectively means that a body is kept breathing and his or her heart breathing for the purposes of harvesting good-quality organs. Although the utilitarian justification for it is considerable, the action taken on its own is 'fairly nasty.'[35]

2.5.3. Instrumentalization

The question of instrumentalization is another significant moral issue that is raised in biomedical research, particularly in stem cell research. The Human Eggs Stem Cell Research (HESCR) may be viewed as treating human eggs in an instrumental way, as means to other objectives rather than ends in themselves.[36] Such instrumentalization is an attribute of property. But if instrumentalization is the objection, then the problem is not the purchase and sale of human eggs but the way in which they will be used. This is an objection to stem cell research itself, which demands the destruction of human embryos in order to extract stem cells. The objection to stem cell research is not to instrumentalization alone. But rather to the combination of instrumentalization with commercialization, which is another attribute of property.

Allowing human embryos to be bought and sold arguably means to treat them as a form of property. For those who will view the embryo as a person, this is as offensive as

slavery. Of course, for them stem cell research itself is equivalent to murder. For those, who do not view an embryo as a fully fledged person, the purchase and sale of embryos could be seen as disrespectful of potential persons. Such attitudes could lead to disrespect for actual person, just as desecration of dead body might breed disrespect for living human beings. Allowing human eggs to be bought and sold could be criticized for the very same reason, namely that it treats the sacred components of human life as a form of property, engendering an attitude of disrespect for actual person. In the context of HESCR, markets in the raw materials of human life would be for the purpose of creating a commercial product, which might ultimately be patented and produce profits. This may be seen as sliding too far towards treating human beings as objects to be fragmented, manipulated, transformed and ultimately sold as commodities. Fragmentation, alienation, instrumentalization and commercialization are the hallmarks of property. But human embryos are not mere biological or clusters of cells. They are the tiniest of human beings. Therefore, we have some moral responsibilities not to deliberately harm them in the name of biomedical research.

2.5.4. Denial of autonomy

Autonomy literally means self-rule. It has been defined as the capacity to think, decide and act freely and independently. Each and every patient has the right to make free decisions about his or her healthcare. For this purpose the patients have to be given all available information relevant to their decision. Privacy, voluntariness, self-mastery, choosing freely, the freedom to choose, choosing one's own moral position, and accepting responsibility for one's choices are some of the ideas associated with autonomy and respect for autonomy. In bioethics many issues are concerned with the failures to due

respect for autonomy.[37] In the medical history there are lots of examples where rights and interest of the patient have been neglected. For example, at the end of the World War-II the world became aware of the monstrous examples of the medical research in the name of medical science by the German and Japanese doctors in Nuremberg. Subsequently, the new famous Nuremberg Code was set up, the first principle of which states that the voluntary consent of human subject is absolutely necessary for human experimentations. Not that only in Germany and Japan the doctors subjected people to experimentation without their consent. Health care professionals in many other nations – including the United States have engaged in practices that ignored the rights or interest of their research subjects. Some 20 years after the end of the World War-II, Henry K. Beecher published an article entitled 'Ethics and Clinical Research' in the *New England Journal of Medicine*, providing evidence that hundreds of patients in United States had been unaware of the risks of the research they participated in, and that hundreds more did not even know they were participating in research.[38] Since the publication of Beecher's data in the mid-1960s, various international, national and professional statements and regulations on human experimentation have been issued, and many countries have set up research ethics committees, in attempts to regulate and oversee research involving human beings. To respect an autonomous agent is to recognize with due appreciation that person's capacities and perspective, including his or her right to hold certain views, to make certain choices and take certain actions based on personal values and beliefs. Such respect has been historically been connected to the idea that every person possesses an intrinsic value independent of special circumstances that confer value. As expressed in Kantian ethics, autonomous persons are ends in themselves, determining their own

destiny, and are not to be treated merely as means to the end of others. Thus, the burden of moral justification rests on those who would restrict or prevent a person's exercise of autonomy. There are various such burdens or issues that we have been facing while exercising autonomy. Some of the most important and controversial issues are: Will consent be sought from potential research subjects? What procedures to obtain consent will be followed? How will confidentiality be respected? The potential research subjects signify here the vulnerable groups. They are not competent, such as when they are unconscious, mentally incapacitated, or too young, to make a reasonable decision. They may be human infants, the mentally disables, and human embryos. How and what consent procedures would be followed with these potential research subjects is a controversial issue still today. Patient's incapacity does not necessarily exempt the clinicians from the requirement to obtain consent. Obtaining the patient's consent to medical care is a legal requirement now-a-days. Law has recognized some ways in the case of vulnerable groups also. In some jurisdictions, if a patient is mentally incapable of making medical decisions, the clinicians must obtain consent from a substitute decision maker.[39] The surrogate decision maker may be the parents/doctors or a researcher, who can decide on behalf of their children or patients. Using this method of consent ensures that people unable to consent are not 'orphaned' by biomedicine.[40] But, as parents are deciding on behalf of their children (of course it is not allowed in UK law), this process is not at all the same as the process of obtaining consent from the person who is the potential research subject. Because, respecting the autonomy of the interested parties signifies precisely not doing what we think is the best for another, but eliciting from her what she believes to be right for herself.[41] Similarly, a person has the right to withhold

consent from taking part in a research project, if she so wishes. She has the right to refuse self- regarding, life- sustaining medical interventions. In order to respond to such situations, the principle of respect for autonomy will suggest considering the circumstances of research project which is acceptable for other principles, such as beneficences and justice. Thus, the controversial problems arise with the noble- sounding principle of respect for autonomy, as with all moral principles, when we must determine precise limits on its application and how to handle situation when it conflicts with other moral principles. Again, if someone's choices endanger the public health, potentially harm a foetus, or involve a scarce resource for which a patient cannot pay[42]- how should one react to such situation? Allowing the fulfillment of such type of autonomy would be dangerous for the society as a whole. On the other hand, not allowing to fulfilling such autonomy on behalf of social wellbeing would limit the enjoying autonomy. If the second point is right, what is that limit and how it is be measured and what standard would be followed to measure? All these questions need to be considered to arrive at a reasonable set of answers. Thus, the principle of autonomy is not absolute. As John Stuart Mill has observed rightly, the personal freedom may legitimately be constrained when the exercise of such freedom places others at risk of harm. In the context of confidentiality also this suggests that a patient's right to control how personal information is shared with others is constrained by an obligation not to harm others. When harm is threatened, the primacy of autonomy, and hence the duty to preserve confidentiality, no longer precedence, and disclosure without the patient's authorization may be permissible or required.[43] This again raises the question: what levels of risk and harm are necessary to disclose the confidentiality without the patient's authorization?

2.6. Critical appraisal: addressing the moral issues

Various guidelines have been formed at national and international levels in different period of time to minimize exploitation of research subjects. The fundamental purpose of research guidelines is to minimize the possibility of exploitation of human beings in biomedical research. But, still the controversy regarding the exploitation of human beings in biomedical research remains fully unsolved. Some of the reasons are[44]-- Firstly, most guidelines are believed to be born in some scandal. They are basically responses to a specific controversy. For example, the Nuremberg code directly addressed the atrocities of the Nazi Physicians. Similarly, the Belmont Report was a response to the Tuskegee Syphilis. Secondly, the regulatory guidance tends not to examine the overall ethics of research, but, to have a specific purpose. For instance, the International Conference on Harmonization has the purpose of creating a common rule for the 'registration of pharmaceuticals for human use'. The aim of this conference was more to enhance the efficacy of drug approved than to protect research participants, for which it differs from declaration of Helsinki. In general, these guidelines emphasized the procedural safeguards of informed consent and independent review by an institutional review board or research ethics committee. However these leave 'paper trails' only that can subsequently be audited. Thirdly, both the above difficulties contribute to a third, that the existing guidance is neither comprehensive nor systematic. For instance, the Nuremberg Code with its 10 statements and the Declaration of Helsinki, originally with 22 principles, subsequently expanded to 32, contain no elaboration. Such sparse, oracular statements lack an overarching framework to ensure that all relevant ethical issues are addressed. They also lack justifications for their claims, implying that the ethical guidance is either

self-evident or beyond debate. Consequently, when controversies arise about whether the principle itself is valid or how a principle should be applied to a case, there is nothing to appeal to other than the authority of these documents. Apart from these there are some other deficiencies also of existing research ethics guidance. And because of these deficiencies, there is a need for a broader, systematic, and comprehensive framework that include an ethical justification and specification for how each principle is to be fulfilled in practice. Among other goals, this framework should incorporate those concerns that overlap in the existing guidance and organize them in a coherent whole. To develop a morally acceptable framework in a balance state of all principles, both the analysis of all the possible moral issues related to human subjects' experimentations, and adequate responses to these issues are essential.

2.6.1. Informed consent

The term 'informed consent' is constituted by two single terms which signify two distinct though interrelated, demands.[45] The first constituent, 'informed' sets forth the demand to recognize the possibility of asymmetry of information between the researcher and the participants of the study. The second constituent, 'consent' sets forth the demand to recognize the principle of autonomy. Thus, the term 'informed consent' demands upon the researcher the duty to recognize the autonomous status of an individual, and the duty to provide the information that would enable agents to understand their choices and consciously exercise their autonomy. It also provides agents (potential research subjects) the right to be treated as autonomous agents, and the right to be provided information to enable them to understand their choices and exercise their autonomy.

Almost from the last 25 years informed consent has been recognized as a necessary as well as sufficient ethical justification for action that effect others, including medical treatment, research on human subjects, and uses of human tissues. There are lots of reasons in favor of the thinking that informed consent is of great importance in medical practices. But most of these reasons are quite unconvincing, because these are based on poor arguments and sometimes these are lumbered with exaggerated claims. O O'Neil in her article '*Some limits of informed consent*' has argued that informed consent has great value or importance in medical practices.[46] Denying the importance of informed consent leads medical practices to the paternalistic tradition which is irrelevant in today's medical sciences. O'Neill succeeds in identifying some important limitations of informed consent in his article, which needs special attention while applying informed consent as a moral principle in medical practices. Both in formal and informal context of our everyday transaction, informed consent serve as an ethically important aspect. No doubt traditionally emphasis on informed consent is confined to more formal context such as signing a contract, getting married etc. But in every day informal context such as shopping and borrowing a book from library, buying a train ticket etc transactions are not questionable if and only if both the parties are aware of the essential features of transactions and take part voluntarily. O'Neill has clearly mentioned that medicine is not the only part of our life in which formality, bureaucracy and explicit ways of seeking, giving, recording, and respecting informed consent have multiplied. There are other parts of life (both formal and informal) as mentioned above where the very significance of informed consent is undeniable. But the fact is that there is no other part of our life except

in medicine, where informed consent causes more difficulty. She has clearly mentioned the underlying reasons of this difficulty in her article. These reasons are as follows-

Informed consent is very much concerned with the competency of the involved subject. One who is not competent may fail to give informed consent properly. Competency can be acquired when we are, as J. S. Mill puts it, 'in the maturity of our faculties'. But the fact is that medical practices deal with a number of such persons who are (temporarily or permanently) not in the maturity of their faculties. Discussions on informed consent in medicine and medical practices turn our attention to this fact. A person cannot give informed consent when he is too young, or very ill or mentally disordered. Similarly, a person, who needs emergency treatment, cannot give informed consent. He may be matured in his faculties. This shows that even in the maturity of our faculties we may not be able to give informed consent in complex medical treatment. So the maturity of our faculties is not the criteria for giving informed consent. There are others conditions which need to be considered while seeking informed consent for permissible medical treatment. Secondly, in medical practices informed consent procedures are useless when it is concerned with selecting public health policies. In so far as public health policies are concerned, they have to be uniform for all, so they cannot be based on individual choices or informed consent. For example, vaccination policies are public health policy. In the true sense of the term public health policies would be undermined if their implementation depends on individual informed consent. Another important limitation of informed consent is that in medical practices personal information's such as family history information, genetic information etc, are often disclosed to the medical practitioners without the consent of all to whom the information

pertains. It is impractical, sometimes even impossible to obtain prior consent to disclose personal information of the patient from their relatives. This fact cannot be reconciled with the claim that informed consent is necessary for all ethically acceptable medical practices. Fourth limitation of informed consent is that people, who are of course competent, may be unable to give informed consent if they are under constraint-for example, prisoners, soldiers, and the vulnerable. They all have the ordinary capacities to consent, yet they cannot. The reason is that they are unable to refuse the other's demand. So they are not to be considered as less problematic in obtaining informed consent in medical practices. The above reasons clearly point out that informed consent is not necessary for all medical practices. Informed consent cannot be obtained from the patients who are incompetent to consent, it cannot be used in choosing public health policies, cannot be secured for all disclosure of third party information, and cannot be obtained from those who vulnerable or dependent. From ethical point of view, informed consent is important for treatment of an individual if he is competent and free to consent. Indeed medical ethics claim that in such cases informed consent is indispensable.

2.6.2. Doctor's duty to care

In medical research harm is justifiable to some extent because it is impossible in medical research to be free from harming absolutely. But harms as such are a bad thing from the ethical point of view. We must resist harms as much as we can. So doctors have a duty to care about her patients or her research subjects. Moral issues arise when the doctors fail to perform this obligation honestly. Doctor's duty to care is related to the therapeutic research as well as with the non-therapeutic research. Therapeutic research is conducted in the context of clinical care. In this type of research the participants are patients

expecting to be treated for their illness as well as to help the researcher gain knowledge which can be generalized. Here, some harm to the research subject might be expected. It would be experienced as a necessary part of therapy. For example, treatment for cancer is associated with risks of some very unpleasant side effects, but the risks are outweighed by the therapeutic benefits, and the two are directly related. If a research project involved giving chemotherapy to a cancer sufferer, harm might be anticipated, but balancing benefit would also be anticipated, sufficient to render the harm acceptable.[47] Here, Doctor's duty to care involves basically the following issues: firstly, are the procedures, which research participants will have to undergo for the trial to reach a successful conclusion, unacceptably risky? If therapeutic research, is there equipoise? If non-therapeutic research, are the risks greater than minimal? In the clinical trial the doctors may not offer the best treatment available, which is the duty to provide. Similarly there may be risks of harm which are not directly related to the therapeutic benefit expected from the treatments received in the trial.

Randomized control trial is set up because either there is some doubt about a treatment which has hitherto been offered as common therapy, because a new treatment is being developed which is thought to be an improvement on any current treatment. The objective and reliable way to show that one is better than another, or at least that one is not the same as another, is by gathering together a group of patients who have been presented with the condition which needs treatment or experimental treatment. Importantly, the allocation of treatments is done not by preference of doctor or patients, but randomly, by the equivalent of tossing a coin. Thus, by the nature of trial design, the doctor will have no say in which of the treatment options in the trial her patients will

receive. From a duty-based perspective, the doctor will need to be entirely happy that such a situation is in her patient's best interests. This entails that she should have no preference for any of the treatments. She should genuinely believe that each treatment option in the trial is as good as any other. This attitude of a doctor towards the treatment options in a randomized control trial is named as Equipoise.[48] There is a distinction between strong and weak equipoise. In strong equipoise, doctors genuinely believe that each treatment option is as good as any other. On the other hand in weak equipoise, the doctor may have a preference, but she does not think that in the end, her preference will be better. Thus, individual doctors may strongly prefer one treatment over another, but as groups there are roughly equal divisions between them as to which is preferable. This attitude is known as community equipoise. However, it may be that only strong equipoise is sufficient for the doctor's duty to care to be honored.

There are different views about the extent to which the setting of a clinical trial is capable of allowing a doctor to act in her patient's best interests which are crucial to the ethics of clinical research. If by putting her patients into a clinical trial, a doctor is acting in their best interest, then the therapeutic research project should be considered in exactly the same way as ordinary therapy. In the ordinary therapeutic setting, certain rules apply which are not currently considered appropriate for research. For example, if a patient is unable to consent (incompetent) and needs treatment, it is legally up to his doctor to act in his best interest. If putting a patient into a clinical trial is the same as treating him in the ordinary way, a clinical trial is currently underway involving patients with his condition, then that patient should be put into the clinical trial, regardless of the fact that he is unable to give his consent, for it is the doctor's duty to enroll him. If, on the other

hand, it is not in her patients' best interest to enroll them in a trial, the incompetent patient will automatically disqualify.

Even if the doctor is impartial as to the treatment choices, does the very act of enrolling her patient in a trial remove the possibility of her treating him as an individual patient in his own right, with specific medical needs and peculiarities? There are two ways to ensure that this loss of care does not occur. Firstly, she should give consideration as to whether taking part in a trial is in his best interests, not just as regards the different treatments but also as regards his personal well-being. She should be able to establish this by asking him whether he would be happy to receive his treatment in the context of a trial. Secondly, the doctor should ensure that the research is designed in such a way that she or her research team can respond to particular medical needs as they arise. The result of the research should not depend upon having to ignore individual medical needs. Another way in which therapeutic research can trouble duty-based morality is that participation in a clinical trial does not merely involve random allocation to a treatment that a patient might have had anyway or to a novel allocation to treatment. It also involves additional tests and measurements, such as urine or blood tests, in order to gain the results of the research. Hence, more is required of the patient in a trial than receiving treatments. These extra tests further emphasize the fact that being in a trial is not the same as receiving treatment in the ordinary way.

The use of placebo in therapeutic research is another issue for duty-based morality. On utilitarian grounds the use of placebo is justified. It adds scientific weight to the design and its inclusion as one of the arms of the study often means that smaller numbers need to be studied, and therefore fewer patients are required to be research

subjects. However, the duty-based requirement to ensure that there is no justification for giving some patients, a worse treatment than others, simply in order for there to be fewer subjects receiving the inferior treatment. The patient for whom the doctor has a duty to care is the patient who is in front of her, not the generality of patient. Placebo is only justified as part of a clinical trial if , as described above , it can be offered by a doctor to her patient in the certainty that this treatment is at least as good as the other treatments. So according to the *World Medical Association Report* (1996, Oct.), where there is no 'proven, available treatment' a placebo arm is justified.

2.6.3. Well defined ethical principles

The historical evidences have shown that various ethical components have been attached to the research or clinical practices on human beings. They can help us improve the research practices. Bioethics is the discipline that has been addressing these ethical components. Though it is a modern term, bioethics is as old as medicine. It is to be noted here that the code of Hammurabi and Hippocratic Oath first introduced the importance of ethical considerations to clinical practices. In addition to ethical considerations, bioethics (as multidisciplinary in nature) concerns the moral, legal, political and social issues raised by medicine, biomedical research and life sciences.[49] But, to understand and analyze the moral issues raised in research practices on human beings, we need an appropriate logical framework that is formed by the study of ethical theories. Three well known fundamental ethical theories are: Goal-based Moral theory, Duty-based Moral theory, and Right-based Moral theory.

According to the goal-based morality theory, goals or consequences determine the rightness or wrongness of an action. In the context of research practices on humans, this theory suggests that it should aim to maximize health and minimize harm. A particular research project is morally obligatory, if its outcomes are useful to maximize benefits and minimize harm. The philosophical idea that works behind this theory is that the proper aim of humankind is to maximize happiness. In the classical formulation it is known as Utilitarianism. This method was first applied to practical problems by Jeremy Bentham (1748-1832). This theory is appealing since it requires no religious faith, no explicit moral code, no general agreement of what rules must be obeyed.[50] It simply asserts the law of nature that is everyone wants to experience pleasure and avoid pain. This theory has two distinct forms: one is rule-oriented and another is act-oriented. According to the former, we should identify those rules which we believe would lead to the greatest happiness. And according to the latter, if we are sure that an action will maximize happiness, then one should be prepared to perform it, whatever it involves. A research project involving human subject is justified from goal-based stand point on the basis of the following reasons-firstly, it is likely to achieve results which can be translated into better medical care for patients; Secondly, if the number of participants is fewer than the number of future beneficiaries; And thirdly, if the benefit to future patients is of more magnitude than the harm to the research participants. For example, at the Nuremberg Trials, (1947) the Nazi doctors used goal-based arguments to justify their experiments. Here, the Nazi doctors perhaps did not try to show that what they had done to their experimental subject was intrinsically good, but rather they tried to show that under the

circumstances their research had to happen, because the consequences of it not happening were much worse.[51]

But there is an inherent disadvantage of this theory that is it can justify or even require harm to some. Hence, it fails to offer a sufficient moral basis for considering whether any given research project involving human subjects is morally justifiable or not. For research involving human subjects to be moral, not only must the consequences of the research be considered, but what procedures and risks the research subjects will be exposed to, and whether the subject will want to be so used must also be thought about. Goal-based morality cannot help us with these concerns. When this approach is brought to the ethics of research on humans, it obliges us to think about two other related issues. First, the research should be designed in such a way that the goals are achieved satisfactorily. Secondly, when the goals are achieved, they should be disseminated. Research project which is not designed properly, gives rise to inaccurate results, which can mislead and are potentially dangerous to patients. Similarly, unpublished results, however accurate, help no one except the researchers. Once research goal has been identified we then have to work out how to achieve that goal in a reliable way. Research which is improperly designed is both a waste of resources and a source of potential harm if its conclusions are wrong and they are believed to be right. Randomized Controlled Trial is the well-recognized method of arriving at an objective answer to some sorts of research question. According to this method no new treatment should be offered outside the context of a controlled trial, so that the treatment's effectiveness and efficacy can be measured, not only for the sake of the patient receiving it but also for future patients.

But, Goal-based morality cannot help us to think about the ethical implications related to the research procedures, because its focus is always on the future. So we need another approach to assist our analysis at this stage, which concerns itself with the contents of an action rather than its results. It is known as duty-based approach. According to this approach, some research which is aimed at highly desirable outcomes may nevertheless be wrong because of what the research involves. The tradition of natural law ethics and imperative moral law of Immanuel Kant are the two formulations of this approach.

According to the former, the moral principles are derived from the observable facts about nature. But, critics say, if natural laws of ethics derive simple empirical observable facts, it would be contested on their own grounds. So natural law ethics suffers from the difficulty of establishing facts of nature. However, in the context of medicine the approach of natural law ethics becomes more meaningful, since it can help a doctor to identify where her duties lies. Although the role of researcher has its functions and associated duties, where research is conducted by a doctor, these do not override the doctor's duties. On the other hand, for Kant, human beings having the faculty of pure reason are bound by the moral law. In his argument,[52] he described that reason is capable of recognizing absolute truth, reason is autonomous. It needs no external assistance to help it recognize what is true. It directs the will. The will, properly directed, expresses itself as the motive of duty. Actions which have moral worth are those which are performed solely from the motive of duty. The motive of duty is determined by the maxim or law. The absolute maxim or law which governs our actions is called the categorical imperative. According to Kant categorical imperative is reasonable in and of

itself. According to his argument, just as a rational being will naturally act according to reason, so a doctor will naturally owe a duty of care to her patients. According to *the World Medical Association Report* (1996)[53] the doctor should not let the researcher zeal for results overcome her primary concern for her patient's well-being. It is a matter of striking a balance. But, it suggests in any experimentation involving human beings', the priorities should be given on the side of patient's interests, not those of science and society.

The doctor's duty to care expresses itself in offering to her patient those treatments which are in his best interests, and avoiding doing anything to him that is harmful unnecessarily. There are different levels of benefit and harm and similarly their justifications are also different. To understand these differences we can separate the research in to therapeutic and non-therapeutic types. This distinction to some extent depends on researcher's intention. Therapeutic research is research which is conducted in the context of clinical care. Here, the participants are patients expecting to be treated for their illness as well as to help the researcher gain knowledge which can be generalized. Some harm to the research subject might be expected here, but it would be experienced as a necessary part of therapy. By contrast, non-therapeutic research will offer no treatment to research participants; they are simply guinea pigs and can expect no therapeutic benefit from being in the research project. However, duty-based morality demands that participants of non-therapeutic research be exposed to no risk of harm, since there is no balancing benefit to them. But it is impossible to remove absolutely all risk of harm from non-therapeutic research.[54] Duty-based approach demands that research should be conducted in such a way that research subjects are not harmed and they will each be

treated as separately important individuals to whom duties are owed, and not merely as instruments to a greater goal.

Right-based morality is another kind of deontological ethics. It can be a useful counterbalance to the duty-based moralist's tendency to be paternalistic. This approach asserts that a patient's wishes should be consulted, since it is her right. Here, it is not the moral health of the researcher we are concerned with, but the interests or rights of research subjects. Immanuel Kant's theory of the autonomy of reason has often been invoked by this approach to support the existence of inherent rights. For him rational being should always be used as ends in themselves, never merely as a means to another's end. Right-based approach can be further elaborated by dividing it into choice theory and interest theory. It demands the need to obtain consent and to respect confidentiality while doing research on human beings. By consent is meant the adequately informed, voluntary agreement of a competent person to participate in research. And, by confidentiality is meant that the non-discloser of private information which has been given in medical context.

The practical value of right based moral approach is that we should always consult the judgments of those who are affected by our actions. In research on humans, it translates into the requirement to consult potential research participants before enrolling them into studies. The right that is in question as regards research on humans can be called the right to self-determination. According to this theory, patients and people in general have a right not to take part in research, if they so wish. In order to identify what underpins the right of a person to refuse to take part in research, we will have to consider

the circumstances of a research project which is ethically acceptable according to goal-based and duty based criteria.

In both ethics and law, there is a widespread consensus that patients have the rights to make decisions about their medical care and also have the rights to be given all available information relevant to such decisions. By gaining informed consent, one can legitimately justify human subject experimentations and make him free from objectifications. The involving subject has a right to know what would happen with him or her in experimentation before giving his consent. It is of course a sign of respect towards individual autonomy or freedom. O'Neill has also established that informed consent has a great importance in medical practices.[55] But the question remains: How far informed consent can secure the individual autonomy, since the very concept of individual autonomy is deeply obscure?

From the above analysis it becomes clear that each theory has their deficiencies to some extent. But the deficiencies of one approach can make up with the help of the other two approaches. Thus, they are complementary to each other. To dismiss one approach would be to lose an important aspect of moral thinking. Apart from these three, there are other theories also in the literature of ethics. But these three theories have been accepted as the model for the purpose of considering the ethical components of research on humans, because these theories can help to develop a framework for ethical review of research projects. So ignoring the one approach by making the other two approaches as absolute, creates a tyranny within which no one flourishes just as making science and its pursuit an absolute creates a tyranny. Goal based approach provides the context; it justifies the research in terms of its outcomes. But there are some research projects which

are too risky to research subjects to be acceptable. So consequence is not the only justification to enroll the research subject. The other two approaches also have to be considered seriously, as far as the involvement of human being in research is concerned since all the three approaches have been playing a very important role in decision making processes of research practices on human beings.

2.6.4. Institutional mechanism

The institutional or organizational mechanism has a very important role in the biomedical experimentations involving human beings. The success or failure of a health care research institution depends on their mechanism or culture. The way an organization operates, the pattern of its behavior, is its culture.[56] The institutional mechanism or culture comprises the pursuing goals and the norms, processes, and rules of behavior by which it seeks to attain those destiny. The ethical climate of an institution is its morale. It includes the expressed values that are actually implemented in its daily operations. An essential requirement for a positive ethical climate of an institution is that it should operate in such a way that society expects it. Here, it needs to be made clear that since the societal expectations are dynamic, so also the mechanism of a health care institution should be dynamic. An institution is of low morale, if it is behaving in ways which is not in accordance with society's expectation of it. It also reflects on the stakeholders trust on the same institution adversely. Culture and climate, which form the overall mechanism of an institution, are very much important for a health care research institution. The systematic approach is now recognized widely in health care professions. It can help to address the difficult ethical situation faced by individuals in medical research involving human beings. The systematic approach in health care also raises the possibility of more

appropriate allocations of accountability within the system. Regarding the systematic-approach, it can be said that-

> A truly systemic view of current health care (in the United states) considers how this set of individuals, institutions, and processes operates in a system involving a complex network of interrelationships, and array of individual and institutional actors with conflicting interest and goals, and a number of feedback loops.[57]

Most of the time, the health care professionals practice their profession in and with health care institutions. Within the institutions, the health care professionals are not the sole decision makers. They cannot take monopoly decision in the institution while facing critical ethical issues related to health. The existing mechanism of an institution will take the absolute decision in such situations. So, it can be said that institutional mechanism of a heath care, can protect the involved subject of research from abuse to some extent. It can be expected if the institutional mechanism is formed in accordance with ethical and societal values. So, the decisions of a health care institution regarding complex medical problem, has great ethical significance. Ethical issues also arise in medical practices due to the conflict of interest between physician and their associated health care institutions. Health care Organizations can also suffer a form of moral distress, when they fail to fulfill their societal obligations.[58]

Advancements of medical knowledge have come about on the basis of research. The safety and the usefulness of all treatment regimes/protocols involving drugs, medical devices, procedures, etc., are derived from the accumulated evidences. In this process, the termed Evidence-Based Medicine (EBM), and the participation of human subjects

(clinical trials) are, in part, unavoidable. Medicine is a regulated profession. Worldwide, it is mandatory to adhere to the statutory regulations and conform to Good Clinical Practice (GCP) guidelines of national and international levels, which have their origin in the World Medical Association Declaration of Helsinki (1964) on 'Ethical Principles for Medical Research Involving Human Subjects'. The fundamental tenet is that in research on human beings, the rights, safety and the well-being of the study subject(s) take precedence over the interest of science and society. An institutional mechanism of health care profession can play a very significant role in taking care of this fundamental tenet. For overall monitoring of the ethical issues of any health care institutions, there should be an ethics committee. Now, the ethics committee is an important and mandatory component of institutional mechanism of health care profession. All medical research will mandatorily need to be approved by a registered ethics committee in the area where the study is to be conducted. The ethics committee should comprise medical, scientific, non-medical and non-scientific members. Its responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a clinical trial. It is interesting to note here that effective from March 2013, the registration of ethics committees has been made mandatory in India.[59] As on September 30, 2013, 576 ethics committees have been registered across India, of which Assam has only one and the entire North-east, only two. It would seem that, in this part of the world, medical research is on its nascent stage, and there is room for public discourse on the way forward.

When medical research is combined with medical care, additional standards are applied to protect the patients who are also the research subjects. The doctor-patient relationship is enshrined in the Declaration of Geneva of World Medical Association

(1948) which states, from the physician's perspective, "health of my patient will be my first consideration," and the International Code of Medical Ethics (1949) that declares, "A physician shall act in the patient's best interest when providing medical care". However, the framework of clinical research is clearly in the public domain, and where the institutional and public overview of clinical research is concerned, the difficult task falls upon the ethics committees to ensure conformity with the internationally-accepted standards.

2.7. **Conclusion**

Today, medical communities have realized that at least some experimentation on human subject is necessary because animals, computer models etc. cannot always play the substitutive role of human subject experimentation. But we should not let the researchers use human subjects willy-nilly in their research ventures. The discussion in this chapter suggested that we need to come up with standard procedures of ethical codes and conducts both at the institutional as well as non-institutional level so that the question of life and livings of human beings is not jeopardized.

Ethical reflection upon human experimentation has led us to the conclusion that knowledge is valuable. And no one can deny it. But this does not mean that we have to give knowledge an absolute priority. Knowledge cannot necessarily give us a good life. The life and living is more important. An ethical life need not necessarily be a knowledge-centric life. However, it is undoubtable that in human civilizational growth the urge for gaining knowledge plays an ostensive role. Therefore, it is important for us to make a balance between the urge of gaining knowledge on the one hand and being

ethical on the other. In this chapter, I have dealt with the ethical concerns of experimentation with humans. I have analyzed various issues that moral philosophers have highlighted while talking about the necessity of experimentation. The following chapter deals with the case of animals. There I shall see what kind of ethical issues are standardly raised and objected in the case of using non-human animals in research and investigation.

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[9] Notes: In 18th century England, Princess Caroline of Wales (later Queen as the wife of George IV) ordered her physician to test smallpox vaccine on six condemned before administering it to her children. An unfavorable attitude had grown in society towards such experimentation at that time. Despite this unfavorable attitude, in 1743 it was proposed that a condemned man in London be subjected to an experiment. The aiming of this experiment was to clarifying whether there is existed some sort of canal between the oral cavity and the ear. There was a gradual change of public sentiment in the late 18th century, consequently the proposal was criticized and ultimately cancelled. (Kevorkian, J. (1985). Medical History. *Journal of the National Medical Association*, 77, 3. pp- 218-222).

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[11] Notes: It was an easy matter to make the slaves to experimentation at will in which the potential for crippling injury or death was entirely irrelevant. The most brutal involved a male slave kept in an open- pit oven to research a new method for treating heat stroke. The most useful, aimed at developing a good surgical technique for the repair of vesicovaginal fistulas was carried out on a slave woman in Alabama. (Kevorkian, J. (1985). Medical History. *Journal of the National Medical Association*, 77, 3. p- 223).

[12] Notes: In the early 20th century, one of the major threats to American life was the yellow fever. At that time, no possible treatment was available to cure yellow fever. The signs and the symptoms of yellow fever were well known, but the cause of the disease remained obscure. Researches were undertaking during that time to know the possible causes of the yellow fever and accordingly its remedies. U.S. army surgeon, Walter Reed, who was a member of the yellow fever commission, undertook a research project to establish the etiology of the disease with his colleagues. By September 1900, the work of the Reed Commission proved conclusively that the Aedes mosquito was the vector of yellow fever. The establishment of the mosquito's role in the transmission of yellow fever offered a solution to the problem of disease, namely eradicating the mosquito and the insect's breeding spaces. On October 27, 1900, the front page of the *New York Times* brandished the headline, 'Mosquito Carries Yellow Fever Germs'. The special report described how the U.S. Army surgeon Walter Reed and his colleagues established that the Aedes Mosquito served as the intermediate host for the so called parasite of yellow fever. (Emanuel, Ezekiel J., Grady, Christine C., Crouch, Robert A., Lie, Reider K., Miller, Franklin G., & Wendler, David D. (2008). *The Oxford Text Book of Clinical Research Ethics*. New York: Oxford University Press. pp- 9-10).

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[14] Notes: Mustard Gas Test was another most inhuman experiment of the U.S. authorities which was tested on prisoners' soldiers through involuntary gas chambers in 1940 s. It was the time when bio-weapon research was at its peak. Even U.S. authorities used their own soldiers in their experiments without bringing anything in their notice.

The Tuskegee Syphilis is another top- rated evil human experiment of the history which was conducted on the Negro males. It was a kind of clinical study that was carried out for decades in Tuskegee, Alabama between 1932 and 1972. The study was conducted on around 399 Negro males. They were mostly illiterate and poor people. They were told that they had bad blood in their bodies which needs treatments.

The Jewish Chronic Disease Hospital Case During the summer of 1963, Chester M. Southam and Deogracia, B. Custodio together injected live, cultured cancer cells into the bodies of 22 debilitated patients at the Jewish Chronic Hospital (JCDH) in Brooklyn, New York. The purpose of their research was to determine whether the previously established immune deficiency of cancer patient was caused by their cancer or alternatively, by their debilitated conditions.

The Hepatitis experiments performed at the Willowbrook State School was normally cited as one of the most serious breaches of research ethics of the post-World War II period. Henry K. Beecher, in his article "Ethics and Clinical Research" published in New England Journal of Medicine, 1966 has vehemently criticized Willowbrook experimentation as unethical. (Emanuel, Ezekiel J., Grady, Christine C., Crouch, Robert A., Lie, Reider K., Miller, Franklin G., Wendler, David D., (2008) *The Oxford Text Book of Clinical Research Ethics*. New York: Oxford University Press. pp- 73-87.)

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involving Human Subjects (Draft: 1982; revised: 1993, 2002); the Resolution 196/96: Rules on Research Involving Human Subjects, NHCs, Brzil(1996); the Medical Research Council Guidelines for Good Clinical Practice in Clinical trials, UK(1998); the National Statement on Ethical Conduct in Research involving Humans, National Health and Medical Research, Australia (1999); the Ethical Guidelines for Biomedical Research on Human Subjects, ICMRC, New Delhi (2000); the Guidelines on Ethics in Medical Research: General Principles, Medical Research Council of South Africa (1977; revised: 1987, 1993,2002)., (Emanuel, Ezekiel J., Grady, Christine C., Crouch, Robert A., Lie, Reider K., Miller, Franklin G., & Wendler, David D. (2008). *The Oxford Text Book of Clinical Research Ethics*. New York: Oxford University Press. p-124.)

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