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CHAPTER 4

MEDICO-LEGAL ISSUES AND PROTECTION OF HUMAN RIGHTS IN MEDICAL RESEARCH.

Personal autonomy which is commonly seen as a fundamental value is compromised, for the welfare of people who stand to benefit from medical research. Even though in many cases the research participant may not immediately benefit from the results and they may be suffer injury consequent to research, but, in the light of remedying the illnesses, research on human beings is equally important.

Damage or death may result due to research if the researcher is negligent. In most medical research human beings are recruited as a try and error test. Thus the medical research with human beings compromises personal autonomy of the research participant for the sake of human welfare.

For the welfare of the humanity at large it is pertinent to focus the health concerns based on the rationale that the health is a worthy pursuit for its own sake and the surest route to moral dimensions and justifications. There is a need to balance the rights of research subjects and the need for advancement in medical science, which is so sadly lacking in many systems of governance.

To organize a medical research including human beings involves different category of human rights concerns pertaining to the welfare of human beings as dignity, bodily integrity, autonomy, and privacy. There is a positive obligation to consider these values and promote medical research to benefit suffering patients for the welfare of the humanity.

History reveals the importance of doing no harm to the consumer of a health sector and medical science even from the period of Hippocrates. The same obligation and duty rest with a researcher when pursuing different ways to conduct medical research. It is crucial to preserve the rights of the research participants relating to personhood for the welfare of the humanity. There are several international legislations specifically safeguarding the rights of the human beings when they are made part of the research or experimentation.
The safeguards to human beings involved in medical research are a matter of most biomedical debates and discussion throughout the world. Certain International Organizations has also issued some guidelines in this area. The Guidelines are given to supplement and to strengthen prevailing rules or legal framework and to act as a physical foundation on which ECs may construct a definite and, strong specific written framework for caring out their actions when conducting medical research involving human beings.

The quality may be brought out in any procedure if there is a well designed guideline. It can also act as international standard setting which may lead to uniformity and adherence to strict and definite legal principles.

UNESCO has issued, in 2005, a declaration which has universal application based on human rights and bioethics. The object of the declaration is to create awareness about medical research and the consequent advantages arising from technological advancement of medical science. Declarations suggest that, research may be conducted based on a foundation of ethical principles.

Dignity, liberty and basic human rights of human beings which are fundamental to every human being may be respected. Regarding medical research the principle which may be taken from the declaration is that the welfare and interest of the society need to be given predominance over the interest of the advancement of science and society.

In advancing scientific knowledge, implied and express advantages to research subjects and other persons who are affected by the research may be maximized. The personnel and body autonomy of persons while taking decisions, may be respected. For individuals with diminished responsibility and incapable of exercising autonomy, special steps may be taken to safeguard their rights and interests.

The declaration also mentions about free consent of the individuals involved in the procedures. The information regarding the procedures may be clear and enough to arrive at a decision. It needs to be on a procedure which can be comprehended by the research subjects. Formalities that are followed in case of withdrawal from the studies may also need to be mentioned in advance.
Consent to participate and to continue may be taken back by the research subject whenever he wants without stating any reason. If prescribing limitations guaranteeing any exceptional principles to the general theory that may be rationalized on an ethical and legal background\textsuperscript{v}.

Declaration suggests that, specialized care may be provided to those incapable to consent to a procedure. Permission and approval to conduct the research may be acquired for the best interest of the individuals. The domestic law on this regard may be followed.

Even though of diminished responsibility the person concerned may be participated in every stage when a decision is made and also in withdrawing the consent. Research may be conducted for the therapeutic benefits of the participants of the research, except according to the permissible limits and safeguarding measures laid down by law.

In cases of research without having any benefit to the research participant. The procedure may be of lesser harm to subjects of experimentation. Protection of the research subject’s basic human rights need to give priority. Denial of a person to be a part of his privacy and need to maintain confidentiality to his health data need to be respected.\textsuperscript{v}

The ethics committee may include members who are independent, having expertise in interdisciplinary subjects and pluralist. The committees may be given the duty to consider ethical, social, legal, and scientific concerns on research projects with humans. Such an ethics committee can furnish advice regarding ethics of issues in a clinical background. They can specify certain rules and can formulate and prepare guidelines. The committee may foster debate, educate and generate public awareness about the relevance and need of medical research\textsuperscript{vi}.

There are many areas in medical research where the rights of research subjects have been questioned. One such situation is when the research subject is unfairly denied certain beneficial medical interventions. When there is already an available medicine approved for a given disease and the research is done for a new medicine for the same disease. In such cases the research subjects are being unfairly denied the available already approved medicine which is essentially a human rights violation.
Legal and ethical effects of Placebos

Placebo is an inert medicine either in the form of powder, pill or liquid which does not have any therapeutic value. In medical research, therapies in the nature of testing the efficacy are usually correlated to placebos for identifying the experimental therapy’s efficacy and potentiality. In certain research, research subjects are given placebo in place of actual medicine or experimental therapy.

Use of placebos which doesn’t have a medical action on the type of ailment or cure for any disease which is under investigation is justified only under certain situations. One being that, presently there is no medication or treatment for the disease under experimentation. Through the administration of an inert pill what the physician / researcher tries to prove is the healing effect of the tested drug beyond that of an inert medicine for a specific time period.

The debate over the use of placebos is surrounded over many ethical and moral concerns. The main criticisms being an accurate treatment which has proved good and effective in that particular ailment is withheld without administering to that research subject. Many consider this as a clear cut violation of basic rights.

The research participant is under the impression that he is receiving actual and effective treatment. Nondisclosure of the fact that what is given as medication is an inert pill forms the basic feature of this type of application. So getting consent while there is an application of an inert pill results in the failure of the basic nature of the therapy. Even partial disclosure is same regarding this aspect.

The ethics of the placebo controlled studies have been debated in the revision process of the declaration of Helsinki. Helsinki Declaration is not clear on the application of an inert pill. What can be interpreted from the wordings of the declaration is that when there is an effective treatment presently available, application of an inert pill is against human rights.
values. There need to be an evaluation of percentage of risk, benefits, burdens, and effectiveness of the new medicine like:

1. The percentage of Benefits: The declaration specifies that the percentage of benefits of the new medicine need to be much high compared to the existing one.

2. The percentage of Risk: On a risk benefit analysis the amount of risk appended with the new medicine or therapy is very low. At the same time percentage of risk with the presently accepted therapy was very high.

3. The amount of Burden: The amount of burden appended with the new therapy is very less compared to the earlier one.

4. The ratio of effectiveness: The ratio of effectiveness of the new medicine need to be very high when compared with the earlier therapy.

5. The declaration expressly mentions these conditions.

Certain exceptions are also considered and recognised. The main exceptions are:

1. No current treatment exist

2. Methodologically and Scientifically sound reason.

3. Essential to determine efficacy or safety of any treatment.

4. Non existence of risk to research subject consequent to the application of placebo.

The declaration cautions that extreme care is needed to avoid the using these option in an abusive manner. Ethical principles may not be violated when taking a placebo group to apply an inert pill. If a new therapy is administered for testing the efficacy of a medicine for an ailment to which presently there is no therapeutic measures are available, but, administering an inert pill brings ethical issues if there is an effective treatment presently available.

When the present therapy is effective in restricting serious harm, it is unethical to use inert pills. Exceptional methods are also followed in certain cases. One example is that of the present treatment has severe toxicity that the patient may not accept it. In such cases the
patients takes the role of a research subject where the doctor becomes a researcher to evaluate the efficacy of a new medicine in comparison with the presently available one.

When a placebo-controlled trial is not combined with serious threat of injury, it becomes ethically proper to design a placebo-controlled trial protocol. Arguments for and against the application of placebos is even though controversial, it is up to the researchers to accept the use of placebo or not.

Application of placebo does not mean that the participant does not receive any therapy. An auxiliary care may be provided similarly as that of the group which receives the active treatment. Placebo-controlled procedures may be carried out as add-on procedures where all research subjects get a standard treatment.

There are guidelines which clearly stated that if an effective treatment is known, placebo group is contraindicated\textsuperscript{vii}. There are certain disorders which have the special features that it always keeps on fluctuating. Only very slight changes are usually seen. Take for example, in case of psychiatric disorders; placebos may be a right choice. When there is excessive delay for treatment in an effective manner, it may prejudicially affect the health of the research subject. There is no evidence that treatment delay results in permanent damage to the patient.

Justification that nondisclosure of the fact that placebos are going to be used don’t result in a harm to research participant is a weak justification. What really happens is that the individual losses one’s own body autonomy\textsuperscript{viii}.

The effects of placebos are pure psychological events affecting the research subjects derivable from the entire circumstances of treatment. The study also shows the effect of an inert pill present in medical practice, even when no inert pill is administered. In addition to this advancement and connection of laboratory and medical research may show improvements in using inert pills in an ethical technique which is silently present in daily health care, and stimulate the use of therapies to influences placebo effects.

Council for International Organizations of Medical Sciences, 2002, Guidelines 11 provides that, the application of placebos is recommendable only when there is no alternative
treatment presently available. The main principle of this international guideline is that when making any experimentation on a condition that may cause death, most appropriate presently available treatment needs to be offered.

If any new process of treatment which was evident as superior to the available one, that may be offered to the control group. The most essential prerequisite of using placebos is that first, it need to be safe and secondly may not cause any irreparable damage.

A placebo preparation may not lead to any adverse consequences. Under this international guidelines two type of disclosure is considered as relevant for application considering the each situation. They are disclosure and non-disclosure. It is also specifically stated that disclosure doesn’t induce any of the participants to consent for which otherwise he would not have consent.

Partial disclosure of the fact that there is an application of an inert pill is not supported by many as they feel that it will scare away the participants from enrolling in the research.

The actual difficulty in the medical research is explained by Kaplan as either it is ethical to have a group dispossessed of the effective treatment, at the same time the other group gets the drug that has the possibility to cure a disease condition. In order to handle this issue we may evaluate certain ethical principles: justice, autonomy, fairness, beneficence, and divergence of views and interest.

The autonomy and beneficence are the standardizing theories that are exactly admissible for this problem when considering whether a placebo controlled trial or an active controlled trial should be conducted. The last two are most appropriate for the behaviour of the pharmacist.

After examining all the literature, it is agreeable that using inert pill in a study is ascertained in a circumstance where no treatment choice exists, if one exists then it’s not productive in the population or the previous study was questioned, or in some sequence of events where the drug does not cause non-life intimidating injury for research participant.
Doctrine of informed consent constitutes placebo controlled trials ethical, as it direct towards all the aftermath of the probable risk involved in a placebo group and in lag of the processes involved in research. At the same time, an active control study is authenticated when a productive treatment prevails where the persuasiveness over standard therapy should, finally be the hypothesis of the study.

Nevertheless, there is still a prevailing controversy due to the divergence in individual beliefs. But without considering this controversy, if a practitioner acts in the good intention of their patients by not infringing the autonomy of the patient, any type of trial should be based on the approvable circumstances.

The researcher is also presumed to be having a standard level of performance which is acceptable with the Nuremberg Code. Thus, as long as the pharmacist ethically without having conflicts of views, a placebo controlled research may also be conducted when it is necessary.

Active controlled trials also are treated as active controlled equivalence trials (ACET) are substitute to placebo controlled studies when its use is not recommendable due to the adverse effects to the patients. The only problem with the ACET is that a null hypothesis is suggestive that the new treatment is as productive as the accepted therapy. To sum up, the placebo controlled trials should be our first preference of research as long as it goes along with Emanuel and Miller’s “middle ground” and Temple and Ellenberg’s policy that appreciate patient’s autonomy and does not beneficenceix.

**Protection of Human rights and Embryonic Stem Cell Research**

Another prominent area in which major human rights violations take place when medical research is being conducted is embryonic stem cells. India is emerging as one of the leading centers for cord blood banks, which can provide stem cells for regenerative medicine because of its large, young population of ethnically and genetically diverse potential donors.

The research with stem cells taken from embryos has tremendous potential to replace tissues that are damaged. This type of research may lead to new and improved therapies for various types of disease especially diabetes, injury relating to spinal cord, alzheimer’s, pakinson’s
The potentiality of human stem cells in medical treatment is enormous. The stem cells consist of features which have the power to reproduce continuously. It functions to renew tissue throughout a person’s life. The word stem cell is generally used to denote cells that renew tissue in organisms that are adult. An example of an early stage stem cell is found in the blood of embryo is hematopoietic stem cell.

Stem cells of this nature have the potential to produce lot of specialized cells or tissue through amplification. Resulting cells may be used to treat injury or disease. Thus because of their ability to reproduce themselves and distinguished with other cell types. The stem cells have the prospects to make treatments based on cells. It enables re-growth of tissues injured by fractures, burns, or any other injuries to cure a different range of degenerative ailments.

Embryonic stem cells can contribute to therapies of various ailments. Patterned creation of big, newer population of cells of humans like, cardiomyocytes and neurons, may generate considerable amount of cells to discover any medicine and transplantation treatments. The research using human embryonic stem cells may provide insights into new progressing instances that may not be investigated directly in the human embryo. It has substantial consequence in medical field, including birth defects, infertility and pregnancy related ailments.

Human stem cells taken from embryos has the potential to decrease the tissue toxicity brought by cancer treatment. It is possible that injection of embryonic stem cell may revive full immunity to patients going through bone marrow transplantation. The embryonic stem cells can generate specialized cell types that are therapeutically effective in animals. Kim and colleges describes how they generated a specific class of neurons from cultured mouse embryonic stem cells and used the neurons to reverse symptoms of parkinson’s disease in rats. Embryonic stem cell research will do more good with regard to the diseases of nervous system. The logic behind this that, firstly most of these disease cause due to deficit of
nerve cell, and secondly the nerve cells that are mature can’t separate to take over from those that are lost\textsuperscript{xii}.

In recent experimental study neural stem cells of human beings was segregated. It displayed sensitive progressive signs. It can transform to neurons when grafted in mice. Such discoveries of methods to produce particular categories of neural cells from Embryonic stem cells shows tremendous hope of therapeutic measures of high neurological disorder for which there is no presently available treatment.

Stem cells are generated in culture to transform into either bone or cartilage producing cells. These cells may then be brought into the injured parts of joint cartilage in instances of Osteoarthritis or into big holes in bone that may come from fractures of surgery. These type of repair may have lots of benefits over the present practice of tissue grafting. Yet another manner in which stem cell research may bring about miracles is that of disorders in blood\textsuperscript{xiii}.

The proteins present in globin are important for the transit of oxygen through the blood. The epsilon globen gene can be seen only in embryonic red blood cells. When this gene turned on in sickle cell patients, it blocks the sickling of the cells that contain sickle cell hemoglobin. Research involving embryonic stem cell may help in finding answer to questions about how to turn on the epsilon globin gene in adult blood cells and there by prevent the disease process. Stem cell has the capacity to undergo asymmetric division. As it serves as a system to repair, they can theoretically divide without limit to replenish other cells. If once a stem cell line is established, it is essentially immortal\textsuperscript{xiv}.

Cell line can be grown in the laboratory indefinitely. Cells need to be frozen for storage. More than any other health – related technology, milestones in the history of the growth of stem cell research shows that future treatments derived from stem cell science seems to hold a promise of ground breaking cures for many diseases, and beyond that for a more or less radical extension of the human life span.

The legitimacy of the stem cell research and the possible ethical and human rights violations emerging out of the stem cell research is very controversial. Producing embryos with the
single motive of research is viewed by many as a further step in the instrumentalization of human life xv.

American biomedical research has taken use of ex utero fetal tissue during 1930’s as an object for medical research. Even many years before scientists have acknowledged the chances of making such cells to produce more specialized cells or tissues, for using in the treatment of diseases such as Alzheimer’s disease, Parkinson’s disease, heart disease, and kidney failure xvi.

Through different experimentations it made researchers to understand the earlier stages of human development. The properties of fetal tissues were used for the generation and experimentations for finding out vaccines, the study of viral reagents, the propagation of human viruses, testing of biological products etc. In 1954, Nobel Price for Medicine was won by American immunologists who used cell lines received out of human fetal kidney cells to grow polio virus in cell cultures. It was an important step forward in the production of vaccines for polio.

In 1960, Research was conducted on stem cell taken from adult tissue. 1980s witnessed the stage when the scientists began researching with implanting brain tissue from aborted fetuses into patients with parkinsons disease as well as patients with other neurological disorders.

In 1981, first mouse embryonic stem cell line established. In 1988, James Thomson isolated human embryonic stem cell lines at University of Wisconsin. He derived ES cells from the blastocyst of an early human embryo donated by a couple who have received infertility treatment xviii. In 1988 itself, pluripotent stem cells were isolated by John Gearheart and his colleagues at the Johns Hopkins University. Gearheart and his team derived stem cells from primordial gonadal tissue obtained from cadaveric fetal tissue. In 2007 registry of human embryonic stem cell lines were established, 15 institutions and 78 cell lines were registered, and eligible for US federal funding, including 10 from Indian from two institutions.

Britain became first country to issue research license for human embryonic cloning to create
stem cells in 2003. In 2004 South Korean Scientists clone 30 human embryos and develop them over several days. UK opened stem cell bank in 2004 itself. In 2005, Dr Hwang and team from Korea develop stem cells tailored to match individual patients but shrouded with controversy.

In 2005 Wisconsin Scientists grow two new human embryonic stem cell lines in animal cell free culture. \textsuperscript{xviii} The Amniotic fluid-derived stem cells, in intermediate stage between embryonic and adult stem cells are another latest catch for researchers. Extracted from amniotic fluid, they grow quickly without turning to tumors, a problem for other types of stem cells.

There are no ethical issues with amniotic fluid derived stem cells as it is derived from waste amniotic fluid and the placenta. In another discovery, scientists, reports that, like any other type of stem cells, cells taken from fat need not to be cultivated for more than two weeks. The benefit of this is that within two hours millions of cells can be prepared for implanting. These stem cells can be easily collected from subcutaneous fat tissue, which produces so many stem cells.

The advantage of such stem cells is that there is no need to grow more stem cells in the laboratory. Blood-brain, barrier, a major challenge in treatment, can be overcome by a new technique involving suspending of stem cells in a particular drug and then injecting them. This breaks down the brain barrier cells, which don’t allow penetration of stem cells. The result is better grafting of stem cells, helping faster recovery with a smaller dose of the medicine. \textsuperscript{xix}

Thus, even though the stem cell research has shown promising results in alleviating human sufferings, and is certain to advance fundamental knowledge, there are many ethical and medico legal issues involved which need to be balanced against the expected results.

The fundamental principles underpinning research on human being have been refined by various human rights instruments. The declaration of Helsinki can be treated as the core factor which influenced for the development of Human rights instruments which focuses on the protection of the individual against abuse and oppression.

All most all human rights documents gives predominance to human beings over the
welfare of the society and advancement of technology. There are many judicial interpretations which cited the declaration as a guide to international legal principles on the conduct of medical experiments. The basis of all principles relating to medical research revolves around the concepts like human dignity, privacy and confidentiality.

The growth in the field of stem cell research resulted in many landmark discoveries. The isolation of human embryonic stem cells and stem cells of various types that have the potential to generate many different cells and tissues is the most prominent one. Presently available sources of ES&EG cells are cell lines that exist in tissues of dead foetus resulting from abortion that are elective in nature or termination of pregnancy by surgical manner or embryos left after treatments of infertility and also from embryos developed with the sole purpose of research.

Several groups oppose the research, saying it is unethical and destroys living embryos. As in all other fields of medical research, the question here is also formulation of a policy and fixing up regulations for doing these researches without infringing the principle of dignity and other basic human rights of the individual. Ethics, philosophy and religion have tremendous effect on the status of embryos and legitimacy of experimentations with embryos.

**Religious and Philosophical analysis about the Status of Embryo**

Developing a policy relating to Human embryonic stem cell research is very much influenced by the diversity of religious and ethical views on the moral viewpoint on the issue of human embryo. History reveals that, earlier there were widespread practices of destroying human embryo. Later on religions started giving better status to human embryo.

Ethical nature and the adoption of human dignity to the possible use of human embryos depend largely on various philosophical and religious thoughts. It is essential to analyze these thoughts before going into various human rights instruments which enumerates the principles to be followed while conducting medical research.

**Christian Philosophy**

The Christian philosophers gave much importance to the sanctity of life of an unborn child and believed that life begins since conception. To the Catholic Church, the embryo immediately after the union of the sperm and ovum, has received its right to life directly from
god, there is no other agent involved. Man has no domain over his life and body. He holds it in trust for god’s purpose.

This belief is based on the conviction that any human being including embryo in the mother’s womb which dies un baptizes is incapable of being rescued from sin. The sacrament of baptism which alone cleanses original sin and provides entry to the kingdom of God. Pope Paul VI, in his Encyclical Humanae Vitae (the value of human life), issued in 196, points out “we must once again declare that the direct interruption of the generation process already began, and above all directly willed and procured abortion, even if for the therapeutic reasons, are to be absolutely exclude as illicit means of regulating birth.

Thus the Roman catholic church opposes research using stem cells derived from embryos, due to certain reason that, making use of stem cells from tissues of aborted foetus that remains following clinical IVF procedures consist of the wilful destruction of a genetically peculiar, living member of human kind. Destruction of Blastocyst is viewed as destruction of a life which has the potential of full moral protection even from the time of conception.

Embryonic germ cell research is also not permissible because it involves the evil of abortion. However, the Roman Catholic Church does not fully disfavour the stem cell research. The religious objection is with regard to the materials from where stem cells are taken. The stem cell may be taken from many other alternative sources which are not immoral, like, miscarried fetuses, placental blood or adult tissue etc.

Islamic Perspectives

According to Islamic perspective, there are several stages through which the life of the foetus evolves. They consider personhood as consequent to several process. Islamic theology beliefs that life begins in the foetus only after 150 days of conception, so destruction of embryo, during that period is not offensive to the religion, but it request the followers to “multiply and prosper” so generally Muslims are against destroying embryos.

Islam recommends and supports generating embryos for the purpose of research. Only condition is that embryos may not be implanted. For causing an abortion Islamic religion requires, a special indemnity to be paid and it devolves up on the legal heirs of the child.

Even though anything done to the foetus after 150 days of conception is against Islamic principles, now a days, as a result of enormous power to make human health better
as a result of this research. A major a major number of believers of Islam agree as it is advisable to take life of the early embryos of human beings for the sole objective of research.

**Hindu and Buddhist Perspectives**

The main principle of Buddhism is ahimsa which does not permit himsa at any cost. But under the influence of shintoism that only after seeing the light of the day**xxv**, the new born baby becomes a human being. So as they believe in such a theology killing the child in the womb is permitted in Japan.

Life of a Hindu is a series of rituals and ceremonial events which signifies their attitude with respect to reproduction and life cycle. Atharvaveda contains references of giving punishment for the destruction of embryo, but the nature is not clear, whether it is criminal in nature or not**xxvi**. Manu declared women who had procured abortion as an outcast or a murderer of husband or of a Brahmin**xxvii**.

Other views where that if a women kills her fetus, she should be abandoned **xxviii**. Nirukta considered murder of bhruna as one of the seven sins**xxix**. Hindu philosophy is completely against killing the child inside the womb. Thus the credibility of research with embryos of human beings differs based on a tradition rooted in ethics, philosophy and religion.

**Jewish Perspectives**

Jewish theology believes that human beings are merely the person employed to manage their bodies which belong to god. There are several principles available in the Jewish theology that is relevant for examining research with stem cells. They believe that an individual is created in god’s image.

Thus the life is really worthy. God entrust the body to human beings with a duty that, health need to be taken care off and life to be protected. Human beings are Gods helpers for carrying out his duties and have an obligation to take any methods to cure from any ailments whether natural or artificial, only the God has the absolute awareness of the aftermath of their actions.

Thus Jewish theology put forward four potential impediments to research with stem cells
taken from embryos.

1. The status of fetus from a moral point of view and abortion

2. Consequent evil and its intensity

3. The commandment to respect the cadaver

4. The status of embryos from a moral point of view

   Judaism believes that, foetus develops into a person only after the 40th day of conception, until then it is “like water”. After this time span it is entitled to some amount of respect and protection. Foetus becomes an independent person, possessing full moral rights only after coming out from the womb during birth.

As Judaism preaches to preserve human health, what is practiced is when either health or life of the women in question due to foetus, abortion is allowed. At this stage of pregnancy, the rights of the woman have more weightage than that of the foetus. The foetus is considered only as a component of a person or a woman’s body. 

   The rights of the foetus become more strengthened after the 40th day of gestation according to the Jewish theology. It is believed that at this stage foetus develops into a person with full moral status and rights. It is homicide to perform abortion after 40 days. Now regarding the question of procuring stem cells from aborted foetuses for life saving purposes, it appears that even though aborting after 40 days post conception is usually acceptable, there is no problem to use aborted foetus as source of stem cells.

   There is also wide appreciation within Judaism that not much harm is caused due to the use IVF embryos as sources of stem cells. Extra-Corporeal embryos have no status under Jewish Law. They have no status of a potential or partial person, as embryos earlier to 40 days are similar as that of water. Thus stem cell research is not considered as immoral under Jewish theology as it can be taken either from extra corporeal embryos or foetus from abortion which are lawfully conducted.

   Thus there is no unanimity among various religions on the issue of research with stem cells taken from human beings. Conservative approach on the status of human embryo may
vary if the benefits of treatment of this research is adequately strong.

**Philosophical Analysis of the Status of Embryo**

When we analyse the issue that does the embryo possess the similar moral position as that of children and adult beings have? , it is not easy to find out an appropriate answer to this question without any criticism. One view is regarding the moral status is that; embryo is a cluster of cells exactly and similarly as that of any other group of cells in human body.

A contrary view on this issue is that, embryos may be categorized and treated similarly as that of children or adults. Edmund D. Pellegrino opines that, it is not proper and arbitrary to give full moral status to an embryo. According to him arbitrariness towards the status of embryos is based on the reality that it may be used for experimentation. He opines that if the question of experimentation was not there, no one may question the ontological or biological reality.

Kant never opined specifically on the morale, rationale and reasoning of unborn child or on the moral status of the child in the womb. Kant tries to find out a moral basis for granting the embryos the status of a full human being. He categorises it as an extreme action of human development. He also comments on no moral status of newborn that it is not proper to give full moral status. Kant considers that persons have the capacity to reason and thus takes autonomous choice which is the essence of human dignity which embryo lacks.

When the debated issue is a morally contests one, it is always better, to take a intermediate position. Thus the embryo gets status as a type of human life, but different from the status given to grown up persons or even children. The general approach considered by those who oppose the embryos as persons in similar moral standing that of children and adults is to pinpoint Psychological or cognitive features which are essential for personhood that embryos doesn’t possess.

Most commonly cited are self consciousness, and ability for reasoning. The gist of the arguments of critics who go against the extinction of human embryos specifies that embryos are very much the part of human body as any other body part and possess the right to live with dignity. It’s human nature itself gives it the status of a person.

**Scientific Considerations**
To produce stem cells from embryos, an embryo may be destroyed at the blastocyst stage. During the first week of the pregnancy, after the fertilization of the ovum to form a zygote, which undergoes mitotic cellular division, a hollow cavity is formed. This hollow cavity marks the blastocyst stage. An embryo is destroyed at this stage to produce embryonic stem cells. The blastocyst contains only a thin rim of trophoblast cells and a clump of cells at one end known as the embryonic pole which includes embryonic stem cells.

Even though the term stem cell is generally referred as the cells within the adult organism that renew tissue, the most basic and special of the stem cells is present in the early stage embryo. The embryonic stem cells have the power to retain the extraordinary ability to form into nearly any cell type. Embryonic Germ Cells, which develops from the primordial reproductive cells of the developing foetus, have properties similar to embryonic stem cells. There is an absolutist view which says that it is wrong to destroy embryos of any gestational age, for any purpose.

On the contrary there is another balancing view which says that, embryo acquires full personhood by gradual stages during the process of development between conception and birth, so for promoting scientific research, it might be ethically acceptable under certain circumstances, to use embryos for research. Around 14 days, after fertilization, appearance of a surface thickening, marks the first visible organ of the embryo. It is possible at this stage for the embryo to split into two, or twin.

If the division is initiated even later, that is after the embryonic disc has formed, cleavage is incomplete and conjoined twins results. So the argument is that during these developmental stages the embryo is not a person as there is no indivisibility or individuality.

Thus according to the theory of natural law full status as that of a human being may be given to the foetus only when it reaches the stage of quickening. This stage is considered as a stage of self motion. Scientifically embryonic development is proved to be a continuous process.

Relying on this claim it may be substantiated that foetus have human status right from the beginning, from the moment of conception. There are also scientific evidences which depicts that the nature of earliest stage of embryo as it possess some form of plasticity.

The value that we place on human life is intimately linked with respect for
personhood, but what constitutes personhood is a matter of moral supposition and not one of scientific fact. Some equate personhood with intellect and with the power to make decisions. If such a view is accepted, young infants will be deprived of the right to be valued as persons.

After conception, normally in the first ten days the blastocyst may divide. If such division happens it results in the formation of twins. Medical science categories such a division of blastocyst as unusual but not an abnormal process. It doesn’t indicate any pathological defects.

When we consider this factor that embryos doesn’t have certain unifying principles of development, attributing full status to it as that of human being is not fully appreciable. A justifiable approach may be to give human status to the embryo at the stage when there is no more chance when there are more chances of such division. From that stage it may be supposed that development as a human being begins.

From this proposition it may be summarized that the nature of the early developmental stage of the fetus gives chances for the researchers to use foetus for the research purpose. On a later stage use of embryos may be restricted on legal and ethical basis.

In Webster’s case, Justice O’Connor opined that, viability is the critical point and pre-embryos are not strictly speaking, either persons or property. It occupies a special corner which entitles them special respect because of their potential for human life. The matter to be taken into consideration is what may be the limit to such cases? The blastocyst is definitely directed towards fuller human development. It is not simply a group of cells to dispose of trivally.

The potentiality of blastocyst to develop into a human being need to be respected. Even if not granting full human status permitted research for developing new and improved medicines are allowable but other uses are not. The use of cells derived from embryos for the purpose of medical research to develop new and improved therapies for human health need to be respected and allowed to be conducted. A new cure for cancer is one thing and enhanced shade of lipstick is another.

The issue of characterizing embryos in a lawful manner has perplexed the courts across a range of contexts and jurisdiction. On the one hand it is not person until born alive, but on the other, it seems inappropriate to simply ignore it altogether. It is essential to arrive at a
balance between competing ethical principles to make a policy relating to research with embryonic stem cells.

Moral status of embryo is not an only ethical consideration, there is also an obligation to do everything possible to alleviate the suffering of existing human beings, if ESCell research has the potential to achieve that, and then there is a moral duty to pursue it.

Thus the moral and ethical issues surrounding the stem cell research are very complex. Considering the anticipated benefit of the stem cell research to the mankind, there are many movements around the world to resolve this issue. There are two competing consideration, firstly, concern of the public about legal, social and moral concerns relating to research with stem cells and secondly value freedom for scientific enquiry for advancement of knowledge.

It is essential to consider both potential risks as well as potential benefits of stem cell knowledge to human well being. If research in encouraged without any regulation, the stem cells may become a commodity that can be purchased from market.

The influential and rich will utilize this technology, not for the treatment and research but may be to misuse the facility. It can also create a class, who can afford to buy such technique, while others will be mere spectators. The life may become a commodity and not a gift of god. There may be no sanctity for life as we believe today.

This is a moral degradation that needs to be made good through adequate and responsible legislative intervention. Legislation in this area may become meaningful only when the question of the status of the embryos in medical research relates to human dignity and right to life is solved appropriately. It is essential to analyze various human rights principles relating to medical research. Those who oppose embryonic stem cell research argues that research on human embryos constitutes a violation of human dignity.

**Human Dignity and Medical Research involving Human Beings**

Human dignity is that feature that gives the people the moral right to confront with the most fundamental questions about the meaning and values of their own lives. 

Human dignity
is a descriptive and value laden quality. It encompasses self-determination and the ability to make autonomous choice. It is subjective in nature as it depends upon people’s belief, religious attitudes, cultural heritage etc.

Before considering the human rights guidelines and legislations specifically for safeguarding human beings involved in medical research, it is essential to look into those documents which protect human dignity. It is the basic right of all people of the country, guaranteed through the explanation made to Article 21 by the apex court.xi

The privilege to enjoy dignity in every phase of life is a right without exploitation stipulated under Article 21. It emerges and embodied as a directive to the state in our constitution. It is mentioned specifically from clauses (e) to (f) of Article 39, 41 and 42. It includes safeguarding the health and welfare of the sections of the society who are working men and women.

It also protects the young children from exploitation. It ensures to provide measures to create exposures for children to grow in a good and better atmosphere. It also ensures to create circumstances of liberty and dignity. Establishing facilities to provide education along with opportunities of employment and also to adopt worker friendly measures and benefits.

These basic needs are ensured to allow an individual to lead a life with dignity. The apex court have emphasised that the government neither state or central has the authority to take away or limit these rights of an individual.

It is essential to take adequate steps to safeguard dignity of human being and basic rights and freedom of persons for the application of biology and medicine. Accepting the liberty to protect the dignity and establishing similar rights for all members of the human race is the basis of liberty, equality and welfare in the world.

All individuals are taken birth without any restriction and have similar rights and privileges. The Socio cultural rights are indispensable for dignity. It is essential for free development of personalityxii. Article 23(3) of UDHR specifies the importance of rights to equal and favorable emoluments to guarantee a dignified life for all human being.
As medical research in most cases is non-therapeutic in nature, the volunteer participant to the medical research may be given a favourable remuneration. Likewise, there are two more backing for a dignified human life in ICESCR and ICCPR. ICESCR Article 13 mentions that education may be for proper growth of personality and dignity.

Ethics and principles of human dignity may be taught in such a way that malpractices for business motives may be avoided and curbed to a greater extent. Then relating to Act 10 of the ICCPR, it is mentioned that every individual prevented from enjoying the liberty may be bestowed with humanitarian considerations. They may be respected for having dignity as a human being.

The injured research participant or the legal heirs of the research participant may be adequately compensated. The dignity and identity of all individuals is a pertinent factor to be considered and forms the core of the values that are emphasised in all most all documents and conventions dealing with medical research with human beings. All the provisions of these conventions need to be interpreted keeping in view the aim of the convention which is to safeguard rights and privileges.

Special protection may be given to those who don’t have the capacity to give consent to research. Article 21 mentions that body of a human being as such, may not be used to generate monitory gain. The protocol of the convention of cloning of human beings specifies about the use of human beings as an instrument to intentionally create a human being which is genetically similar to human beings is against the principles of human dignity and thereby results in a controversy in biology and medicine.

It is this declaration that brought the issue of human dignity as an important one for scientific progress. Article 2 stipulates that, every person has the privilege to claim the right to be respected as having dignity. This privilege is without considering the genetic features. It is from this provision the right to be respected as a dignified individual arises. The respect towards unique features and diversity.

Thus, almost all documents particularly dealing with genetics and medical science, the importance is given for safeguarding human dignity. There are many dimensions in which the concept of human dignity may be described. Sometimes it is the source of human rights, sometimes explaining the features of the human rights or some other times elucidating the objects to be safeguarded and sometimes establishing or limiting the rights to exercise
autonomy over oneself. Human dignity is a concept with a long history. It has been employed in both religious and secular traditions. It has been used in many senses my moral and political philosophers.

The dignity very much connected to the inherent merit and utility of persons, as it is incorrect to consider persons as bare matters instead of absolute and independent entities. Immanuel Kant describes the concept of human dignity as all individuals may lawfully affirm recognition from the society and have correlative right and duty to safeguard one another. Humanitarian consideration itself is a concern towards issue of dignity. In medical research human beings are not always used as a means but many times are utilized as an end.

Thus every human being has dignity and owes an obligation to respect others as dignified persons. Again, human dignity can be viewed from two respective regimes from a duty led regime and the other from rights led regime. In a duty –led frame work, both duties to others and duties to one self will be considered.

Everyone has a obligation not to sacrifice one’s own right also process a duty to preserve oneself with dignity. When we analyze dignity attributed to human beings from a rights arising from moral perspective, importance is given to the capacity to select freely and act for purpose. Every human being has correlative rights and duties with regard to one own liberty and welfare.

The convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine 1997 is the foremost agreement on Biomedical Technologies. The aims and objectives of the convention is protection of individuality of all human beings. Article 4 mandates every procedure in the medical field. Medical experimentation also may be conducted with regard to concerned professional considerations and criteria. Certain safeguards are made for protecting those individuals who cannot give consent. One among them being any intervention may be made for the person’s direct benefit.

The Convention points out several methods through which consent may be attained when they are incapable to give a valid consent. The convention specifies that the individual
concerned may participate in the procedure of informed consent, when research is conducted with minors. Views of the minors which are relevant may be given importance with respect to their age and the percentage of maturity. There may be a privilege of withdrawing the authorization at any phase of the research for the best interest of the participants of experimentation.

The convention specifies that the authority of a parent over the research participant who is a child is not power, but the responsibility to take care and take actions for the welfare and best interest of the research participant with good faith. The convention asks for a specific attention to safeguard the welfare of individuals not able to consent and also of embryonic research.

The general rule relating to research is stipulated in Article 15 as the fundamental principle for research involving human beings. The essential features are highlighted as a research without any hindrances. The consent need to be given after getting all information of the proposed study. The consent need to be express, clear and written by the research participant. Medical research may be conducted only when certain conditions are satisfied as per the specifications given under Article 16 of the convention like,

1. There is no substitute for the proposed research with humans.

2. There need to be a proper balancing of the risk and the potential benefits arising out of the research.

3. The scientific merit of the research may be approved after examination by the competent body. A multidisciplinary review may also be conducted to evaluate its ethical acceptability.

4. The research participant needs to be given information on the rights and the various measures to safeguard their protection.

5. Getting informed consent is an essential condition and that need to be documented. The research participant may be given the freedom to withdraw the consent at anytime.

The research with an individual who have diminished responsibility and not able
to consent may be taken only if all the requirements of Article 16 are full filled. The person on whom the experimentation is conducted may be informed of their privileges and the rules for their protection lay down by law. The outcome of the research may produce substantial benefit to the research subject. It is also essential to note that the person concerned may not object the research study xliv.

Article 17 also provides for an exceptional and protective condition prescribed by law that, even if research may not produce direct advantage to the person not able to consent to research, that may be conducted with the fulfilment of certain stringent conditions. It is pertinent to note that when research is conducted on persons not able to consent, it may have the aim of contributing, through significant improvement to the scientific understanding of the individual’s conditions, disease, or disorder.

The research may entail only minimal risk and minimum burden for the individual concerned xlvi.

Article 18 stipulates a situation where the legal framework permits research with embryos only when adequate safeguards are provided to the embryo. It is also provided that the creation of embryos of human beings for the purpose of research needs to be prohibited. The provisions of Article 18 don’t restrict medical research with supernumerary embryos which has been created solely for purpose of fertilization. Any discrimination levelled against a person because of the reason of his genetic background is prohibited by Article 11 of the convention.

The positive implications and activities of medical research and medical science need to be supported and appreciated but only through protecting human rights and dignity; otherwise it may damage the image of medical research and curtail the advancement of medical science. Respecting the human dignity involves maintaining confidentiality.

Confidentiality and Medical Experimentation Involving Human Beings

Confidentiality of the subjects study related records are very important. Confidentiality of the records of the research subjects is also an element of informed consent.. There are many controversy arguments to the effect of how to confront the issue of privacy and confidentiality.
From a consumers point of view any procedure of research is a violation of privacy of an individual. The reason behind such an argument is when the right to confidentiality of a research subject is well protected; it may restrict the easy access to health information of the research participant.

Safeguarding privacy of an individual and maintaining confidentiality and ensuring health are certain concepts which always go parallel. The research subject may have proper trust and belief on the researcher or the research institutions. Only when there is a trust that the personal information they share may be kept confidential the participants of the research may peacefully participate in the study.

The right to confidentiality derived from right to privacy which has its roots in right to dignity and autonomy. The basic feature of the information is that, not to use that information for a purpose other than that for which the information was given. There are several elements in the action for breach of confidence relating to medical research like, does the public interest defense stretch to cover medical research? Is explicit and specific consent necessary before a research subject can be said to have authorized the use of confidential information for medical research? Etc.

Generally it is accepted and justified that the purpose of the disclosure is within the grant of the original grant of the information. Disclosure beyond this purpose is thus unauthorized by the original grant and constitutes a breach of recipient’s duty. The confidential nature of information derives through the application of the principle of beneficence. It protects in restricting harm to research subjects. It also diminishes resulting injury due to the disclosure of the information.

Personal information of a private or confidential kind is also regulated by the common law of confidentiality. The statement by Megarry J in *Coco v AN Clark (Engineers) Ltd*\(^{dvii}\) outlines the following three requirements in a breach of confidence claim:

1. The data has adequate value to be treated as confidential.
2. The data was passed on to the defendant in a situation rendering a duty to maintain it as confidential.
3. The information passed on a confidential manner was used by the defendant without the permission of the plaintiff.
Confidentiality is only one among the numerous aspects emerging from the doctrine of privacy. The protection of personal confidences serves an important social purpose in that it protects interpersonal relations from the risk that one of the parties may abuse information communicated.

For fixing a duty of confidence on the recipient of the information, there need to be some quality to the information passed and that need to be passed in circumstances which requires an obligation of confidence. Confidentiality involves control over who has access to information.

*Breen v Williams* presented the High Court with an opportunity to reassess the law of fiduciary obligations. The appellant’s (Ms Breen) claim was that the relationship of the doctor and the patient was fiduciary in nature and therefore a doctor is obliged to act in best belief for the wellbeing of the patient. Ms Breen’s assertion was that doctors were obliged to give their patients access to their medical information. The High Court unanimously refused to expand fiduciary obligations to include this type of duty on the doctor.

The trend towards computerization of health care information’s generates confidentiality concerns with respect to computer sabotage committed by persons gaining unauthorized access to computerized record system. Legal rules do not vary with the medium on which patient records are stored. The obligations on a fiduciary are intended to secure a loyalty that ensures that actions by the fiduciary treat the principal’s interests as paramount.

A fiduciary cannot have an interest or inconsistent relationship with a third party where there is a real and sensible possibility of conflict. A fiduciary also cannot obtain an advantage or profit from property, powers, confidential information or opportunities offered by the principal. Same confidentiality principles apply to paper records and computer based patient records. Whatever may be the medium, duty is imposed on the doctor to respect the confidences of his patients.

Most ancient reflection of the right to confidentiality can be found in ancient Greece. About 2400 years ago an oath was formulated in Greece by Hippocrates. The code consists of two parts. The first part consist of the relationship of apprentice to the teacher. The second is
the ethical code. It requires doctors to treat the information elicited from the patient as “sacred secrets” about which they must “keep silence”. This obligation of the doctors to keep the information as confidential appears in all modern codes of conduct.

A claim of a breach of this obligation will succeed only if it is established that, firstly the information given to the doctor had necessary quality of confidence. Secondly, it was given in such a circumstances which importing an obligation of confidence, and thirdly, there is an unauthorized use of those information.

The doctrine of breach of confidence evolved into the present structure in the midst of the nineteenth century. In Prince Albert v. Strange, the Lord Cottenham LC, opined that, an action for breach of confidence is equally sustainable on grounds of equity, confidence and contract law. The Tsaknis opines that breach of confidence is a notoriously ill defined cause of action. Its jurisprudential basis is obscure.

The cause of action having been claimed to arise at one stage or another from property, contract, bailment, trust, fiduciary, relationship, good faith and unjust enrichment. Information can generally classified into three types based on the way, mode or method in which it is being used. It can be personal, business, governmental likewise; all these have something that is common the confidential nature. The underlying purpose for protecting information in each of these desperate categories is undoubtedly different from one another.

Informed consent may also be understood as the procedure through which the research participant decides whether to give access to their privacy and autonomy. It is through this procedure itself that a consensus is arrived for dealing with confidential information which affects the dignity and privacy of the research participant.

Confidentiality refers to data and to the control of handling data regarding them. It is through entrusting the duty of confidentiality on the physician the patient’s privacy is secured. The cornerstone of the relationship between the doctor and the patient is the concept of confidentiality.

The knowledge that the information which they share may remain confidential gives the research participant some form of relief. It is an expansion of the doctrine of privacy. Relating to privacy and data protection, World Medical Association has issued Declaration on
Ethical considerations regarding Health Databases 2002.

Declaration specifies that, the privilege of privacy encourages individuals to take control on taking advantage from the personal data which one considered as private. It is through the application of the doctrine of confidentiality, the privacy of the person’s confidential data is preserved. It has been very much accepted that maintaining confidentiality is very much essential in medical practice.

This is similar in the case of medical research. It is pertinent to create a relationship based on trust and confidence between the doctor and the patient. In case of researcher and the research participant this forms an integral factor. A knowledge and an acknowledge that the privacy of the research participant will receive respect gives him a satisfaction to reveal his confidential information about the health with the researcher which otherwise he hesitate to do.

WMA since its formation has given importance in preserving privacy and dignity to those confronting with health care sector. Even after the death of the patient WMA through its declaration of Geneva points out that the confidential data of the research participant need to be kept strictly in a confidential manner.

Declaration of Helsinki provides specific provisions for the protection of life and basic human rights of the research participants like:

1. Safeguards for protecting privacy of the research participant.

2. Safeguards for maintaining confidentiality of the research participant’s personal data.

3. Safeguards to minimize the aftermath of the study on the research participant.

4. Safeguarding mental integrity and individuality of the research participant.

5. Proper information need to be given to the research participant concerning objective, procedure, sources of financing the research, information regarding the research institution.
6. Probable consequences of the research and the risk and benefits of the study also need to be informed to the research participant.

The research participant needs to be informed of the privilege to withdraw their participation from the research at any time during the course of the research without any hindrance. The researcher may obtain or ask the research participant consent to participate in research only if full disclosure is made regarding the research preferably in writing.

Patients have the privilege to get what data researcher possesses including information regarding health database. In the situation of withholding any information from the patients the physician may be able to give proper explanation for such act. The declaration maintains the importance of the right to confidentiality. It states that, doctors are personally under a duty to keep the information of the individual health data they possess on a confidential nature.

Schemes for protection may be employed to ensure fairness, using the data without proper authority, accessing individual health information in medical reports. It is also essential to maintain measures to ensure authenticity and credibility of the data. In cases of transmitting data, it is essential to ensure that the transmission is secure.

The whole problem of confidentiality arises because the information was disclosed to another in the confines of the confidential relationship. The information was shared because there was trust and confidence between the two parties. There was an understanding that the information may not leak or may not be made public as it may prejudicially affect the relationship.

For the purpose of medical research confidentiality includes, maintaining privacy of research participant especially their individual identity and all medical data from persons other than what is prescribed in the Protocol. The right to confidentiality as in the ordinary circumstances cannot be an absolute one in the case of medical research also.
The liberty to get the results of the study by the general public can also be a right. To maintain transparency and to avoid misuse and malpractices, publication of the research result is necessary. Indian good clinical practices specify that the principle of confidentiality need to be maintained on the sponsor’s proprietary information to unauthorised persons.\(^\text{ii}\). 

EU Directive 2001/20/EC mandates to maintain confidentiality whenever they gain access to confidential information. The objective of the directive is to establish uniform laws on medical research conducted inside the EU. The main backbone of the directive is principles enshrined in Oviedo Convention. The provisions of the convention specify that:

1. With regard to the research with adults who can give consent, safeguard need to be taken regarding privacy and individual data of the research participants.

2. In the cases of those who are not able to write, procedure needs to be maintained to join the research with oral consent. In such cases the consent need to be expressed in the presence of one witness. Procedures may also be adopted to meet the insurance coverage of such research participants to indemnify the liability of the researcher or research institutions.

3. In case of research conducted with minors, minors need to be informed regarding the procedures of the research. This is in addition to the information given to the guardian or parents who lawfully given authorization to participate in research.

4. Incitements to participate in a medical research may not be in the form of any monetary advantages. Accepting compensation is an exemption.

5. In cases of paediatric research, the ethical review of the research protocol may be supported by an opinion given by a paediatrician.

When research is conducted with adults who are incapable of consenting to the research procedure, similar to the provisions made to the minors, certain safeguards to be followed are prescribed.

1. Such research may be allowed only in situations where there is a threat to the life to that person in question.
2. Adequate measures need to be made to reduce pain, and other risk throughout the research procedure.

The Directive also specifies that medical research on minors need to be excluded when it doesn’t have any direct benefit to them. The ethical review committee may also look into certain specific criteria before approving the research to be conducted. The main parameters are the qualification of the researcher and the premises to conduct the research.

Directive also makes provisions regarding who shall apply to the respective national agency for getting approval of the protocol. It is specified that the sponsor of the research may apply and not the researcher.

There was big criticism against this provision. The main argument levelled by the critics was that, this provision very much favours the business motives of the pharmaceutical companies. There are much chances of ignoring relevance of public participation. They argue that this may limit the freedom of research.

Reuse of tissue is another case which the concerns of privacy and self-determination may arise. Lots of body fluids are taken as samples during the procedures of diagnosis in which only very few is taken for diagnosis. Samples which are remaining are usually stored in the laboratories so that it may be made use later for the direct interest of the donor. These left over body tissues are also used for academic and experimentations. Usually it is done without the consent of the patient.

Not giving consent to the reuse of the tissues that are remaining after the procedure is mainly because of three reasons.

1. There may be nothing left over for the patient himself if everything is used for other purpose.
2. It is a breach of privacy
3. The consumer of the health sector has the full liberty to make an opinion on what procedure may be conducted with his body material.

This argument may also be rebutted by saying that we need to choose between whether to discard or use it for advancement of medical science which may finally result in some finding
to benefit the humanity at large. In practice self determination over everyone’s body tissue is very less.

Lots of cells are degenerating from our body in every second. Excretion is done, urine is passed, hair is cut and nail removed. No one shows any signs of attachment to these left over body parts. Nobody wants to keep those under control. The argument is that we need to treat the left over tissue similar as that of other leftover body parts.

Patients need to be aware, in cases of their health data are preserved on a data base and that may be used for certain needs. Consent of the patient is needed if the information stored in the data base is accessible to a third party. Under certain circumstances, individual health data is entered and recorded without the consent of the individual.

One example of such a case is when it is mandated through relevant national law dealing with the requirement or when there is an approval of ethical review committee. In these circumstances it is better to give the donors the awareness about the possible uses of the samples of their body parts even when the patients don’t have the right to object. Cases in which the patients make serious objections on disclosing their data to others, their views may be respected subject to other conditions.

**Conclusion**

Permission from the legal guardian or the parent of the patient whose health data is essential before the data stored on databases may be available to third parties. Conditions for permitting sanction may follow certain rules of confidentiality. Consent from an ethical review committee primarily constituted for these issues, may be attained for all research using data of the patients, even in cases of research which was not envisaged at the time of collecting of data.

An essential and pertinent measure that may be adopted by the review committee in these circumstances may be to inform the patients and make adequate measures to take consent or whether it is adequate to use the data for a different reason without again receiving consent
from the patient. The committee's decisions may be in a manner confirming with the law of
the nation which is applicable to this situation. Information accessed may be used only for the
matters for which approval has been provided.

All those who accumulate, disclose or access health information need to be subjected under
an obligation to follow an enforceable duty to keep the information secure. Publication of
medical research results is having as much importance as that of maintaining confidentiality
and protecting privacy, dignity and the human rights of research subjects.
Article 3 – Human dignity and human rights.

Article 4 – Benefit and harm.

Article 5 – Autonomy and individual responsibility.

Article 6 – Consent.

Article 9 – Privacy and confidentiality.

Article 19 – Ethics committees

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xxxvii Ibid.


xl Francis Mullin's case[1981] 1 SCC 608

xli Article 22 of the UDHR.

xlii Article 17 UDHR.

xliii It is commonly known as The Oviedo Convention.


xlv Article 17 The Convention on Human Rights and Biomedicine (ECHRB) 1997

xlvi Article 17 , Ibid.


xl ix (1849) 2 De G &SM 652.


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