AN EMPIRICAL STUDY ON THE LEGAL ISSUES SURROUNDING EMBRYONIC STEM CELL RESEARCH IN INDIA

Written by ***Purnima Sivaraman***

Advocate, Chennai High Court, Chennai, India

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ABSTRACT

The discovery of stem cells particularly embryonic stem cells with its possible clinical application has generated great curiosity amongst medical professionals and general public. Embryonic stem cell research has become a challenging issue for biomedical scientists, policy makers and regulatory bodies. The key controversial issue is the determination of moral and legal status of the embryo as embryo stem cell research involves retrieving embryonic tissue from spare embryos leading to their destruction. This embryo that has the full capacity to develop into a human being is sacrificed for the benefit of others. Global regulations monitoring stem cell research are also troubled with similar ethical and moral issues associated with it. The main source of embryonic tissue is the spare or supernumerary embryos created during infertility treatment by artificial reproductive techniques (ART). Sadly, in absence of regulatory provisions to govern them, the field of ART is open for all forms of medical malpraxis bearing direct implications on embryonic stem cell research. This article is an attempt to seek clarity on the concept of embryonic stem cell research and contentious issues associated with it.

This is a non-doctrinal study. The researcher has depended on both primary and secondary data. Random sampling has been used to collect the primary data which has been analysed using Frequencies, Chi-Square test and Crosstab method. Secondary data like books, websites, journals and case laws have also been referred to provide a comprehensive and holistic approach towards the study.

***Keywords*:** Embryo, Stem Cell Research, Right to life, Moral and legal status of embryo, Artificial Reproductive Technique.

INTRODUCTION

Stem cells are one of the human body's master cells with the ability to grow into any one of the body's more than 200 cell types. They are unspecialized and undifferentiated cells capable of self-proliferation, migration and differentiation. The distinct characteristic associated with the stem cell is their potential of self-renewal and capacity to differentiate into specialized cell. In short, they are immature precursor cells with the capacity to specialize and differentiate into a mature specialized cell.

Stem cell research has offered a new viable therapeutic option for debilitating diseases, injuries and other diseased conditions. The scope of stem cell-based treatment has expanded in recent years due to advances in stem cell research and technologies. Now, stem cell-based treatments have been established as standard clinical care in certain disorders like use of hematopoietic stem cells in leukaemia or use of limbal stem cells in corneal disorder. Stem cell technology is speedily increasing within the field of regenerative medicine, granting DE novo production of functional tissue and providing for brand new diagnostic and therapeutic capabilities that will surpass the risk benefit ratio of typical existing reparative treatment modality1[i].

The immense potential that has been shown by stem cells in treatment of diseases traditionally considered "degenerative, incurable and irreversible" such as diabetes, heart disease, spinal cord injuries, Parkinson's, Alzheimer's disease has brought them into the spotlight. Techniques have been developed for the *in vitro* culture of stem cells, providing opportunities for studying and understanding human embryology.

Whatever promising future clinical application it holds, stem cell research especially embryonic stem cell research is associated with ethical, social and legal controversies.

What is so unethical about embryonic stem cell research? The major conflicting unethical issue identified with this research is extraction of embryonic stem cells by embryo destruction. The very embryo which has the capacity to become a human being is destroyed at the onset of its

potentiality of becoming one of us. The current view about any clinical research is to look it from the viewpoint of cardinal research principles of autonomy, justice, non-malfeasance and human dignity. Any research which stands to violate these principles is bound to suffer from moral and ethical controversies. Research that involves embryo destruction will find it difficult to accommodate itself within these cardinal principles.

The aim of the study is to address the legal and ethical issues surrounding embryonic stem cell research in India and to study the legal and moral status of a human embryo. The researcher has also tried to analyse the need for a definitive legislation on embryonic stem cell research.

REVIEW OF LITERATURE

Over the last decade, much progress has been made in the differentiation of human germ cells from both human embryonic stem cells (hESCs) and human iPSCs (hiPSCs). A recent report indicated that hiPSCs can be differentiated into primordial germ cells (PGCs) via use of bone morphogenetic proteins. (Panula et al. 2011)

One key issue is the need to assess the function of induced germ cells; this implies the need for research that tests human induced sperm and eggs to determine if they can successfully participate in fertilization and produce normal embryos. (Francis 2009) For example, generation of sperm and eggs positive for specific male and female germ cell markers and negative for those specific to pluripotent stem cells should be ensured. Additionally, appropriate epigenetic programming, properly imprinted sperm and egg chromatin, and appropriate organization of the sperm and egg nucleus and mitochondrial structure should be evaluated. (Dodds) Thereafter, the creation of human embryos may, as a final biological assay, be exceptionally necessary in a preclinical stage to ensure safety of the induced cells. Currently, many countries allow derivation of hESCs from surplus in vitro fertilization (IVF) embryos, subject to some conditions, but many jurisdictions limit or ban production of human embryos for research purposes. (Robertson 2001)

This raises the question of where and under what circumstances the research necessary to explore the medical potential of human induced germ cells can be legally and ethically

performed. Should such cells be brought to the clinic, a different set of controversial issues will appear. (Devolder 2015)

In fertility clinics, ART generally begins with ovulation via hormonal stimulation followed by oocyte retrieval for IVF. In cases of male infertility, the use of intracytoplasmic sperm injection (ICSI) is often required to produce viable embryos with one or a few sperm. Following fertilization, embryos are cultured, generally for 3–5 days, and one or more is selected for transfer to the uterus. (Chen et al. 2009)

When we are able to generate germ cells from human pluripotent stem cells or somatic cells, people may benefit, both from making ART possible in cases where few or no eggs or sperm are produced and from improved understanding of and treatment for reproductive failure. (Trounson and DeWitt 2013) In addition to issues of physical safety, the possible uses of human germ cells differentiated from pluripotent stem cells raise the possibility of perplexing new ethical, legal, and social issues. (Science, ethics and policy challenges) Some technologies that were once considered controversial, such as intrauterine insemination and IVF, are now considered and accepted as mainstream, with an estimated 5 million births aided by IVF to date. (Lomax and Trounson 2013)

India is a key player in the stem cell sector with significant government investment in this area and research activities including the creation of new embryonic cell lines and publication of scientific papers (Inamdar et al. 2009). While these efforts have been commended nationally and in the international community, significant concerns began to emerge from the mid-2000s over unproven stem cell treatments being offered in clinics with apparently little by way of regulatory oversight (Jayaraman 2005). In 2014, it appears that the Indian government has responded to these concerns by announcing legal changes that would, in theory, outlaw stem cell therapies given the absence of clinical trial evidence of their safety and efficacy. (Padma 2006)

The Indian stem cell sector sparked significant social science interest from the mid-2000s onwards with several studies concluding that the governance vacuum in India was a result of the lack of *statutory* regulation of stem cell activities. (Patra and Sleeboom-Faulkner 2009) In 2007, the Indian Council of Medical Research (ICMR) and the Department of Biotechnology (DBT) jointly issued a set of *Guidelines for Stem Cell Research and Therapy*.

These recommending guidelines have two inherent defects. One, these guidelines do not have any legal effect and second, it has no penal provisions for violating the rules/policies mentioned in these guidelines. Multiple approaches to governing health care in India are now emerging beyond those represented by statutory laws alone. (Srivastava and Morgan 2014)

The basic fundamental right to life is guaranteed by Article 21 of the Constitution of India. It says that no person shall be deprived of his life or personal liberty except according to procedure established by law. Even here the term "person" is not defined.

The Indian Legal System provides for the protection of the rights of the foetus through sections 312 to 316 of the Indian Penal Code (IPC) which deals with miscarriage[ii]. In these penal provisions, the unborn child is protected from any act which prevents it from being born and also provides punishment for causing its death which is considered equivalent to culpable homicide.

Section 416 of Code of Criminal Procedure (CrPC) Act 1973 provides for postponement of capital sentence of pregnant women and also to commutes the sentence to life imprisonment in such circumstances[iii]. This provision is made to protect the life of unborn foetus as it has nothing to do with the act committed by the pregnant woman. Here the legislation has considered the unborn foetus as a distinct and separate individual/entity with the right of protection against potential harm.

The Section 13 of the Transfer of Property Act, 1882 deals with the transfer of property for the benefit of unborn. Here the statute has defined the unborn as legal person by fiction.

From the above legal provisions, it is clear that the unborn foetus is protected against potential harm in the same manner as the fundamental rights of non-interference with personal life and bodily integrity guaranteed to a human person. If embryo is granted the status of personhood, then they too will have the right of not to be harmed or killed with imposed obligations of not to do so.

The lack of clarity on the status of the embryo and deliberations put forth by constitutions of various countries and decision given by competent courts it can be assumed that the foetuses are not a person and hence cannot enjoy fundamental constitutional rights meant for human beings or persons. Though the IPC and CrPC provide protection to the foetus from potential

harm the Indian Constitution is silent on this aspect of extending the fundamental rights to the unborn foetus in clear terms.

TYPES OF STEM CELLS

Embryonic Stem cells are the first differentiation after fertilization of cells of the embryo proper. They are derived from the inner cell mass of the blastocyst, 4 – 5 days after fertilization. Adult Stem Cells are derived from bone marrow, peripheral blood, tissues, muscles, adipose tissues, cartilage etc. Umbilical Cord Blood Stem Cells and Placental Stem Cells can also be isolated from the umbilical cord blood and placenta. They are multipotent in nature. Induced Pluripotent Stem Cell are adult cells that are engineered or reprogrammed to become pluripotent i.e., to behave like an embryonic stem cell. Ways have been discovered to reprogram somatic cells to a primordial state and then re-differentiate them to tissues of choice (Takahashi and Yamanaka 2006). It is important to note that though IPSC technology as enormous potential, it is still at its infancy, and certainly does not do away with the need for ESCs (Yamanaka 2009). Human Embryonic Stem Cells (HESCs) Sources are derived from the inner cell mass of the human blastocysts. Blastocyst is formed five days after fertilization of the egg by the sperm. It has outer shell which matures and if survives implantation becomes placental tissue and the inner cell mass becomes the tissues of the human body. The extraction of HESCs from inner cell mass for research purpose leads to the destruction of the embryo. The major source of human embryonic stem cell tissues are the spare or supernumerary embryos created during in vitro fertilization as a part of infertility treatment. The other source is creating embryos with somatic cell nuclear transfer techniques (SCNT).

The legislation of most countries including India allows use of spare or supernumerary embryos either fresh or frozen created during in-vitro fertilization. Some countries with more liberal view have allowed creation of human embryos with SCNT as a source of embryonic tissues.

VALUE OF EMBRYOS

The spare embryos which are the outcome of infertility treatment are the essential source of embryonic tissue. These embryos can either be used for embryonic stem cell research or can be discarded as leftover material once the objective of infertility treatment is achieved. In other words, should we consider them as waste material or treat them as valuable commodity. "For donor couples, the transformation of embryos from intended babies, to 'waste' or 'leftover' material and then finally a source of precious stem cells is a complex and value laden process." (Waldby 2002) The transformation of discarded embryos into stem cells has been referred to by one scientist as the process of turning 'garbage into gold' (Thompson 1995).

The child intending couples have to make emotional, physical and financial investment to reap the benefits in terms of successful pregnancy though this beneficial outcome cannot be always guaranteed. The so considered 'waste materials' has economic value considering the initial substantive financial and emotional/physical cost incurred by these donors. Also, the potential commercial value associated with the result of embryonic stem cell research using such embryos might be tremendous. Pharmaceutical and Biotech companies will earn substantive commercial profit that may eventually flow from this work. This raises an important question about the right of the donor couple to seek or claim financial stake or compensation.

Nevertheless, it is illegal under the Human Fertilization and Embryo Act (HFEA) of the United Kingdom (UK) for them to incur any financial reward for donating their embryos and they have no financial stake in any materials or procedures developed from their donation.

However, the issue of making payments to gamete donors or embryo donors remains ethically controversial as it may lead to "commodification of the body".

GLOBAL LEGISLATION GOVERNING EMBRYONIC STEM CELL RESEARCH

Legislation governing human embryonic stem cell research is not uniform and varies from country to country[iv]. Most of them have allowed use of spare or supernumerary embryos created during in-vitro fertilization for this purpose but have prohibited creation of human

embryos specifically for research purposes. The use of spare or excess embryos is subjected to certain provisions like informed consent, donation of embryos without financial compensation and restrictions on the use of embryo not beyond fourteen days. Few countries have put prohibitions on buying and selling of gametes, fertilized eggs, embryos and foetal tissues. But some countries with more liberal view have allowed creation of human embryos for research purpose with somatic cell nuclear transfer technique as well as use of supernumerary embryos for procurement of human embryonic stem cells. India has allowed establishment of new HESC lines with spare, supernumerary embryo with prior approval of the Institutional Committee for Stem Cell research and Therapy (IC-SCRT) and Institutional Ethics Committee (IEC) provided appropriate consent is obtained from the donor as per the draft guidelines.

PROBLEM OF THE STUDY

The question raised here is if a human embryo should not be given the same respect and right to life as a living human adult. The controversial issue in embryo research is concerned with which embryos are suitable and can be used for research. There is disagreement over whether it is appropriate to create embryos solely for research purposes, and what techniques should be used to create those embryos. Many people and governments feel that an appropriate restriction on embryo research is to limit the use of embryos in research to those embryos that are surplus to infertility treatments.

RESEARCH METHODOLOGY AND MATERIALS

This is a non- doctrinal study. The study mainly focuses on the status given to a human embryo. The methods of the study are analytical, descriptive and comparative. The research is applied and quantitative in nature. This paper depends on both primary and secondary sources. Questionnaire method was employed to collect the primary data for the survey. The types of questions asked in the survey were fixed alternative i.e., the respondents had to choose from specific set of answers.

The secondary data was collected from books, journals, articles and e-sources. The researcher has also utilized commentaries, treatises, notes, case laws and other writings to incorporate the various views of the multitude of jurists, with the intention of presenting a holistic view.

STUDY AREA AND SAMPLE SIZE

The survey among individuals from various socioeconomic backgrounds to trace the awareness of consumers regarding online shopping. A random of 1355 samples have been selected to analyse the awareness of human embryonic stem cell research in India. The primary data has been analysed using Frequencies, Chi-Square test and Crosstab method.

TABLES AND CALCULATION

For the present study, a survey was conducted on each issue in the study area. Cross Tabulation and Percentage method has been to determine the responses of the samples. Chi-Square test has been used to determine the hypothesis. If the pearson value of 'Asymp. Sig' is less than 0.05, then the alternate hypothesis is considered and if the pearson value of 'Asymp. Sig' is greater than 0.05, then the null hypothesis is considered.

Frequency Table:

Educational Qualification					
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	UG	806	47.4	47.4	47.4
	PG	455	26.7	26.7	74.1
	Metric	233	13.7	13.7	87.8
	Illiterate	207	12.2	12.2	100.0
	Total	1701	100.0	100.0	

Based on the frequency table, it can be ascertained that majority of the respondents (87.8%) are literates and have had access to at least the basic education.

HYPOTHESIS

H_0: There is no association between the educational qualification of the respondent and their view on the status given to a human embryo.

H_1: There is an association between the educational qualification of the respondent and their view on the status given to a human embryo.

TABLES

Cross Tabulation:

EDUCATIONAL QUALIFICATION * Do you think human embryo should be given the same respect and right to life as a living human adult?					
Count					
		Do you think human embryo should be given the same respect and right to life as a living human adult?			Total
		Yes	No	Maybe	
EDUCATIONAL QUALIFICATION	UG	339	208	169	716
	PG	151	106	112	369
	Metric	56	60	32	148
	Illiterate	52	36	34	122
	Total	598	410	347	1355

(Table 1)

Chi-Square Tests:

Chi-Square Tests			
	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	15.284[a]	6	0.018

Likelihood Ratio	14.734	6	0.022
Linear-by-Linear Association	2.954	1	0.086
N of Valid Cases	1355		
a. 0 cells (0.0%) have expected count less than 5. The minimum expected count is 31.24.			

(Table 2)

Survey Results:

From the Table 1, it is clear that majority of the respondents are of the opinion that human embryo should be given the same respect and right to life as a living human adult.

The Pearson Chi-Square Statistic (given in Table 2) is 15.284 and the corresponding value is 0.018. Hence, alternate hypothesis is accepted.

DISCUSSION AND IMPLICATIONS

An association can be traced between those who have completed their schooling and their view on the human embryonic stem cell research. It can be seen that 40.5% respondents who have completed their schooling feel that the human embryo should not be given the same respect and right to life as a human adult.

Those who have stated ‘maybe’ show that there are in an ethical dilemma about ‘embryonic stem cell research’. This might also suggest that these respondents want a balance i.e., the embryos maybe used but the right to life must be preserved in the appropriate cases.

It can be deduced from the Pearson value (given in Table 2) that the alternate hypothesis is accepted. This does not reject the null hypothesis completely as there is no conclusive evidence to prove the alternate hypothesis. This is because majority of the respondents, regardless of their educational qualification prefer that the human embryo be given the same status and respect as a living adult. The respondents are of the opinion that despite the benefits of embryonic stem cell research, an embryo must not be used. This indicates that they might not have an awareness on the benefits of human embryonic stem cells or they are still having apprehensions because it is against their religious beliefs and ethics.

The extraction of embryonic tissue for research purpose involves destruction of the embryo. Most of the arguments about the rightness and wrongness of embryo destruction are based on the moral status of the embryo. The moral wrongness associated with embryo destruction will not only make the research impermissible but also deny the potential benefits expected from this research. The use of human embryonic tissues for research poses a moral problem as it brings two highly valued but conflicting moral principles: the inherent duty to provide treatment to ease pain and suffering on one hand and the value of human life and dignity on the other.

Extraction of stem cells from human embryos violates the second principle as it leads to destruction of potential human life. Both principles cannot coexist together, but which principle takes precedence is a rather contentious issue.

DECIDING THE MORAL STATUS OF THE EMBRYO

It's very difficult to ascertain the moral status of the embryo as it varies. There are different views about this moral status. The leading views deliberate that the embryo has the status of Persons, or Potential persons, or Divine creations, or Subjects of moral harm, or the beginning of human life with intrinsic value, or organic material with no moral standing than other body parts. Some people believe that as soon as a baby is a conceived, the foetus acquires the status of a person and should not be killed as it is a gift given by God. This view is largely supported by people with absolute religious faith. The other group of people favour the embryonic stem cell research[v].

The embryo in its early stage is a cellular structure and don't have the psychological, physiological, emotional and intellectual characteristics that we tend to attribute with individuality. It, therefore, follows that if human embryo does not fulfil the criteria for personhood; it does not have any interests to be protected and thus may be instrumentally used for the benefit of other human persons.

In the discussion about embryo research, there are two concepts, namely, pre-embryo and embryo proper[vi]. Here, pre-embryo is supposed to refer to the early stages of the embryo and people believe that it is not the proper embryo and can be used for research purposes. This has

been opposed by many as they feel that this is a rhetorical concept brought into facilitate embryonic stem cell research (Mulkay 1997). Some research workers argue that the formation of central nervous system should be considered as the landmark for the definition of life, since this implies that the possibility of sensation initially exists[vii]. It is argued that the early-stage embryo is not sufficiently personalized to possess the ethical and moral weightage of personhood (Walters 2008).

There is another viewpoint of the "relative value" of human embryos, more than cells but less than persons. This view states that embryos deserve respect but not to the same extent as a fully developed person. In accordance with this argument, the moral status of a human embryo increases in a stepwise manner through its development in the uterus, and at the point of birth it is entitled to enjoy full rights of human beings[viii].

From the entire deliberations one can conclude that the human embryo deserves respect but it cannot be considered as a person as it lacks the essential attributes of personhood.

LEGAL AND CONSTITUTIONAL STATUS OF THE EMBRYO/UNBORN FOETUS

The Universal Declaration of Human Rights (UDHR) in its Article 1 says that: "All human beings are born free and equal in dignity and rights"[ix]. The word "born was used to exclude the foetus and embryo from granting human rights. An amendment was proposed and rejected that would have deleted the word "born", as it was deliberated to protect the right to life from the moment of conception (Copelon et al. 2005)".

Even the Convention on the Rights of the Child does not recognize the right to life until birth[x]. Thus, a foetus has no rights under UDHR.

The main standard for the protection of human life in general international law is Article 6 of the Covenant on Civil and Political Rights (CCPR). Article 6 of the CCPR, in its first paragraph the norm prescribes that "every human being has the inherent right to life. However, the phraseology of the norm doesn't outline the term "human being" (Robertson 2010). The unborn foetus has full potential to become a human being in right environment.

The liberal interpretation of the above fundamental right, one can conclude that the unborn foetus, from the conception till birth, has a right of life and it is immaterial whether the foetus is created in vitro or in vivo. Now, if this standard were transferred to all forms of unborn life, not only would research with embryonic stem cells infringe upon Art. 6 CCPR, but the legality of liberal abortion laws would also be highly debatable.

The US Supreme Court has never ruled on the constitutional status of embryos outside of the body and most US states have no law on the matter. But the court has ruled that foetuses are not persons within the meaning of the 14th Amendment, and thus do not have constitutional rights as such. Presumably that ruling would also extend to embryos as well.

Article 4 of the American Convention on Human Rights states: "Every person has the right to have his life respected. This right shall be protected by law and, in general, from the moment of conception. No one shall be arbitrarily deprived of his life". But the Inter-American Commission on Human Rights, one of two adjudicatory bodies that interprets and monitors compliance with the American Convention, has clarified that this protection is not absolute."

Article 2(1) of the European Convention on Human Rights provides: "Everyone's right to life shall be protected by law." The European Commission on Human Rights, in Paton v. United Kingdom[xi], held that the Convention language "tend[s] to support the view that [Article 2] does not include the unborn," and acknowledged that recognition of an absolute right to life before birth would "be contrary to the object and purpose of the Convention."

In Vo v. France (Plomer 2005), the European Court of Human Rights, which interprets and monitors compliance with the European Convention, affirmed that "the unborn child is not regarded as a 'person' directly protected by Article 2 of the Convention and that if the unborn do have a 'right' to 'life,' it is implicitly limited by the mother's rights and interests, including her rights to life, health, and privacy." The above judgement brings forth another controversial issue of foetal rights versus maternal rights of autonomy. The liberalized abortion laws existing in different countries and so proposed by various organizations have clearly determined the precedence of maternal rights over foetal rights.

CONCLUSION AND SUGGESTIONS

The possibilities offered by adult and embryonic stem cells in the treatment of various diseases have created widespread excitement globally. The clinical application of stem cells and its outcome is not yet clear and hence their potential use need to be ascertained by evidence before accepting them as safe and effective treatment. Though stem cell-based therapies are in early stage of clinical development later on they may turn out to be expensive in nature and thus affordable to only wealthy few. This might create social injustice and inequality and both are in violation of basic principles of clinical research.

The challenge is to ensure that it is available to all patients who need them. The issues related to the source of embryonic tissues still lie unresolved and many more are likely to appear especially if non-embryonic sources of pluripotent stem cells become available. The science of medicine is always evolving and any new scientific discovery is associated with some or the other ethical or legal issue. Ethical issues will remain, but they are the issues that arise in bringing any new discovery out of the lab into clinical research and then clinical use. The more apt and liberal use of ethical and legal principles will help to resolve them and bring these discoveries in reality for the benefit of needy patients.

The human embryo should, thus, not be given the same respect and right to life as a living adult as it has still not attained personhood and it can become a human only if it gets a womb. In many cases, the embryos are thrown away. Such embryos can be used as they will cure certain incurable diseases. But this can be a reality only when the legislations are in place. This is to ensure that human embryos that have the potential to get a womb are not killed. We should strive for a balance.

To summarise the discussion in this article, it can be said that while there has been a severe debate on the ethical, moral and legal aspect of the use of stem cells as a potential cure, it is hard to ignore its potential benefits. In the current scenario where the embryo must be destroyed in order to obtain the stem cell, it is advisable to look for an alternate resolution to this.

The alternate resolution can be found in the form of "induced pluripotent stem cells" (iPSC's), this is a form of re-programmed cell. It reduces the destruction of human embryos by instead using adult stem cells and changing their characteristics to suit those of Human embryonic

Stem Cell (hESC). This new advent though untested, if successful will open the gates to a new era, providing a cure for some of the incurable diseases of now.

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ENDNOTES

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