

Embryo Freezing and Donation: Ethical-Legal Issues

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Abstract

Embryos have been successfully frozen for decades for the purposes of fertility preservation and donation. Embryo freezing and donation is a well-established and successful form of assisted reproduction treatment when both partners are infertile. The first pregnancy was reported in India in 2009 after the transfer of embryos generated from frozen– thawed oocytes. The commercial creation and sale of embryos has raised a chain of ethical-moral questions regarding the rights of the unborn children – their right to know their biological parent, moral status of embryos, how embryos should be handled in the event of divorce, etc. Some feminists and others have viewed the sale of eggs, and presumably embryos, as commodification, arguing that such markets cheapen human life. The disposition of unused embryos also raises moral and ethical dilemmas not only for the couples who create them but also for society as a whole. In India there is no law to regulate commercialization of embryo. The proper guideline should be made immediately to reduce the nature and extent of commercialization of embryos in India. This paper is an attempt to analyze the ethical-legal issues related to embryo freezing and donation.

Key words: oocyte cryopreservation, egg donation, moral-ethical issues, ART

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I Introduction

ETYMOLOGICALLY, THE term embryo comes from the Greek noun *émbryon*, which means *ingrow*. According to the Stedman's Medical Dictionary, the embryo is an organism in the early stages of development, from conception until the end of the eighth week.¹ Embryo freezing is still not very popular in India. Former Miss World Diana Hayden, 42, gave new hope to women who wish to delay their motherhood, when she gave birth to her first child born out of her egg that was frozen eight years ago. Using donated embryo in India is usually a matter of secrecy as couples do not want their infertility revealed and disturb the social and biological connection between the mother, father and child.² The use of donor gametes, either in the form of donor sperm or donor oocytes, is common practice in ART. The development of *in vitro* fertilization (IVF) and related techniques has made oocyte and embryo donation another option for infertile couples.³ It is now possible to take oocytes, or eggs, out of a women's body, fertilize them with sperm and create an embryo in a laboratory. The embryo may then be transferred by the doctor into a woman's uterus, possibly resulting in a pregnancy and eventually the birth of a child.⁴

The use of donor sperm can be traced to the 1800's. In the mid-1980s, oocyte donation was started. During the 1980s, clinical use of IVF and associated research involving human embryos spread quickly among the developed nation.⁵ The advent of *in vitro* fertilization (IVF), followed shortly by embryo cryopreservation, transformed both the medical and legal landscape involving reproduction.⁶ The large majority of embryo donors are couples who have completed their families through IVF and have had the spare embryos cryopreserved. Prior to 2002, the

¹ Maria Aluás, Claudia Diana Gherman, *et.al.*, "Is the Human Embryo Legally Defined and Protected? Causes and Consequences" 58(2) *RJME* 695-700 (2017) available at: <http://www.rjme.ro/RJME/resources/files/580217695700.pdf> (Last visited on 23.01.2018).

² A, Bharadwaj, "Why adoption is not an option in India: the visibility of infertility, the secrecy of donor insemination, and other cultural complexities" 56 *Soc Sci Med* 1867-1880 (2003) cited in A. Widge, J. Cleland, "Negotiating boundaries: Accessing donor gametes in India", 3 (1) *F, V & V IN OBGYN* 53-60(2011) available at: <https://www.ncbi.nlm.nih.gov/pubmed/24753849> (Last visited on 23.01.2018).

³ Claudia Borrero, "Gamete and Embryo Donation" in Effy Vayena, Patrick J. Rowe, P. David Griffin, "Current Practices and Controversies in Assisted Reproduction" Report of a meeting on "Medical, Ethical and Social Aspects of Assisted Reproduction" held at WHO Headquarters in Geneva, Switzerland 17-21 September 2002, World Health Organization Geneva, 2002, available at: <http://apps.who.int/iris/bitstream/10665/42576/1/9241590300.pdf> (Last visited 23.01.2018).

⁴ Sandhya Srinivasan (ed.), *Making Babies: Birth Markets and Assisted Reproductive Technologies in India* 74 (Zubaan, New Delhi, 2010).

⁵ Michael Mulkay, "Rhetorics of Hope and Fear in the Great Embryo Debate" Vol. 23 No. 4 *Social Studies of Science* 721-742 (Nov., 1993) available at: <http://www.jstor.org/stable/285730> (Last visited on, 08-12-2017).

⁶ Susan L. Crockin and Howard W. Jones, *Legal Conceptions: The Evolving Law and Policy of Assisted Reproductive Technology* 25 (the John Hopkins University Press, Baltimore, 2010).

success rate of live births from frozen eggs was 1-3% globally, with few babies born from frozen eggs over decades of attempts.

The use of a donated embryo in assisted conception was first reported by *Trounson et al.* in 1983, when a female patient was successfully treated using an embryo created from a donor egg and donor sperm.⁷ Though few couples are comfortable with embryo freezing and donation, many have moral and ethical dilemmas regarding the freezing and donation of embryos. For those that believe that life is created at the moment of conception, each frozen embryo represents a life and, if unused, a life unfulfilled. The commercialization of embryos has raised a variety of ethical-moral questions regarding the rights of the unborn children – their ability to know their biological parent, moral status of embryos etc.⁸ Embryo donation is an accepted method in assisted reproduction techniques in many parts of the world, for example in the USA, Australia and in European countries such as Belgium, Greece, Russia, Spain and the UK.⁹ Some feminists and others have viewed the sale of eggs, and presumably embryos, as commodification, arguing that such markets cheapen human life. Some individuals believe that embryos have greater moral standing than do gametes.¹⁰

Although there is no law to regulate assisted reproductive technology in India there are non-binding guidelines issued by the Indian Council of Medical Research (ICMR) which called as National Guidelines for Accreditation, Supervision & regulation of ART clinics in India 2005 (hereinafter referred as ART Guidelines). These guidelines envisage the regulation, licensing, and supervision of clinics *inter alia* engaged in assisted reproductive technology or research on human embryos.

II Embryo Freezing

Egg freezing, also known as mature oocyte cryopreservation, is a method used to preserve a woman's reproductive potential. Eggs are harvested from ovaries, frozen unfertilized and stored for later use. A frozen egg can be thawed, combined with sperm in a lab and

⁷ Fiona MacCallum and Heather Widdows, "Ethical issues in embryo donation" available at: <https://www.researchgate.net/publication/289382390> (Last visited on 24.01.2018).

⁸ Robert Klitzman, Mark V. Sauer, "Creating and Selling Embryos for "Donation": Ethical Challenges" 212(2) *Am J Obstet Gynecol* 167–170 (2015) available at: <https://www.ncbi.nlm.nih.gov/pubmed/25448512> (Last visited on 24.01.2018).

⁹ Viveca Söderström-Anttila Tuija Foudila Ulla-Riitta Ripatti Rita Sieberg, "Embryo donation: outcome and attitudes among embryo donors and recipients" Volume 16 Issue 6 *Human Reproduction* 1120–1128 (June 2001) available at: <https://academic.oup.com/humrep/article/16/6/1120/619501> (Last visited on 24.01.2018).

¹⁰ *Supra* note 8.

implanted in uterus (in vitro fertilization). Cryopreservation of excess embryos is a widely practiced part of assisted reproduction techniques in centers performing IVF cycles. Well-functioning cryopreservation systems have made it possible to replace only a small number of embryos at a time, and to freeze surplus embryos for future use.¹¹

The first pregnancy was reported in India in 2009 after the transfer of embryos generated from frozen– thawed oocytes. A 29-year-old woman with previous bad obstetric history and an abnormal karyotype, necessitating a donor oocyte programme. Embryos were generated by microinjection of frozen–thawed sperms into thawed human oocytes (intra cytoplasmic sperm injection). This resulted in a healthy male baby with a birth weight of 2.54 kg which was born by cesarean section at 35–36 weeks of gestation with normal follow-up.¹² The ART Guidelines in India incorporated provisions for embryo freezing. Section 1.6.8. of ART Guidelines provides that:

Facilities for cryopreservation are an essential component of an ART clinic as they are to be used under a variety of conditions such as those described below. Men, who are likely to suffer from psychological stress at the time of ovum pick-up or those who cannot be present at the time of ovum pick-up, are recommended to have their semen frozen for use at the appropriate time. One of the important reasons for freezing semen from donors is that any donor semen has to be quarantined for six months. The safety of using frozen sperm has been abundantly proven, both by experimental work and the actual results in humans. Matters of concern are the donor's health and the necessity to avoid donors who are infected with venereal diseases, hepatitis B or C, or HIV. One of the drawbacks of sperm freezing is an approximate 20% loss in motility after thawing. Donors whose semen is frozen for future use are required to report to the semen bank six months after donation to be checked for HIV, HBV or HCV infection/disease status.

Embryos are routinely cryopreserved to enable storage of supernumerary embryos, as up to a maximum of only three embryos is allowed for transfer to avoid the risk of multiple pregnancies. Human embryos can be successfully cryopreserved at any stage from zygote to blastocyst, using 1, 2 propanediol (PROH) or dimethylsulfoxide (DMSO) for zygotes and cleaved embryos and glycerol for blastocysts. The formation of ice crystals is of concern during embryo freezing. Using programmed, slow freezers reduces this problem considerably, and slow cooling

¹¹ *Ibid.*

¹² Priya Selvaraj, Kamala Selvaraj, *et.al.*, “Successful birth of the first frozen oocyte baby in India” 2(1) *J HRS* 41–44 (2009 Jan-Jun) available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2700691/> (Last visited on 24.01.2018).

is the most widely employed method. Human embryos are known to survive a simple ultra-rapid procedure of fast cooling but there is not much data on the efficacy of these techniques when used routinely. Straws or ampoules used for freezing embryos should be carefully and permanently labeled for identification purpose. Patients should be fully informed before the treatment cycle on the procedure of cryopreservation, the risks and, particularly, what is to be done with their embryos if they do not use them. They should sign a consent form concerning the agreement for embryo freezing as well as for the future use of the embryos. When a serum supplementation is used in the preparation of freezing and thawing solutions, one must carefully avoid any risk of viral transmission to the embryo through the serum.

Oocyte Cryopreservation is the procedure which has been successfully used in cases where a large number of immature oocytes have been retrieved during ovum-pick-up. The oocyte can be thawed at a later date, matured in vitro and used for oocyte donation or similar procedures either on the person from whom the oocytes were retrieved or on other prospective recipients. However, the success rates in terms of fertilization, pregnancy and live births with the use of cryopreserved oocytes are not very encouraging. Much remains to be learnt on identifying the optimal stage of oocyte development when cryopreservation would be of value.

Surplus embryos and donor sperm are cryopreserved. If the woman has become pregnant with fresh embryo transfer, then the surplus frozen embryos are preserved for a maximum period of 5 years, in case the woman wishes to have a second transfer. The age of the woman is taken into consideration, while considering the duration for which the embryos are to be cryopreserved. For example, if the age of the woman is more than 35 years, the duration of embryo cryopreservation is reduced to 2 years. But they are never destroyed, even if the couple does not desire a second transfer. These embryos are then used for donation to infertile couples who need them. Alternatively these embryos may be used for stem cell research. An informed written consent from the donor partners is mandatory. In exceptional circumstances, ownership of the frozen embryo in the event of death of one or both partners may become a controversial legal issue. The concept of sperm cryopreservation for AID became popular in India after the introduction of embryo cryopreservation in IVF programs. Prior to this, AID was performed with freshly donated semen.¹³ It has been estimated that there are 400,000 embryos frozen and stored

¹³ B. N. Chakravarty, "Legislation and Regulations Regarding the Practice of Assisted Reproduction in India" *Vol. 18 No. 1 Journal of Assisted Reproduction and Genetics* 13 (2001) available at: http://pubmedcentralcanada.ca/pmcc/articles/PMC3455813/pdf/10815_2004_Article_229353.pdf (Last visited on 24.01.2018).

since the late 1970s. In reality, the actual number of frozen embryos is probably closer to 500,000 with an additional 20,000 embryos added yearly. Medically, the lifespan of a cryopreserved embryo is unknown. The effect of the freezing process is also unknown on the quality of the embryo if brought to term.¹⁴

III Embryo Donation

Embryo donation is a family-building option for a group of couples in which the woman has premature ovarian failure or is a poor responder to traditional ovarian stimulation, and the man suffers from severe disturbances in gamete production. Embryo donation may also be indicated for couples who are carriers of a hereditary disease which may cause significant morbidity in the child.¹⁵ An egg donor is a woman who contributes her genetic material, usually for reproductive purposes, to another. A donor does not intend to be a parent of any resultant child and waives any rights.¹⁶ The donor remains anonymous, as does the recipient. An informed consent has to be signed by the donor confirming that he will have no legal right to a child born by insemination of his semen sample. The donor is screened for HIV, HBSA, and genetic diseases. Donors are usually college students. The semen samples are frozen and are used after 6 months provided that the second HIV test is negative. The same donor's semen sample is not used to produce more than 10 children; otherwise there could be a probability of consanguineous marriage among the children born by such a procedure.¹⁷

There is no limit to the number of times that a woman might donate her oocytes, unlike the case of sperm donors, where the limit is set at a maximum of 10 pregnancies as per the ART Guidelines. Donor oocytes are used in premature ovarian failure, women with natural menopause who have lost their only child, repeated pregnancy wastage with chromosomal structural abnormality, repeated fertilization failure, and poor responders in an IVF stimulation protocol. Donors should be married women less than 35 years old and must have at least one child.

¹⁴ Peter A. Clark "Ethical Implications of Embryo Adoption" in Craig S. Atwood and Sivan Vadakkadath Meethal(ed), *PSCB-AMMM* (July 2, 2014) available at: <https://www.intechopen.com/books/pluripotent-stem-cell-biology-advances-in-mechanisms-methods-and-models/ethical-implications-of-embryo-adoption> (Last visited on 24.01.2018).

¹⁵ *Supra* note 9.

¹⁶ Margaret E. Swain, "Oocyte Donation: Legal Aspects" in J.M. Goldfarb (ed.), *Third-Party Reproduction: A Comprehensive Guide* 32 (Springer New York 2014) available at: [file:///C:/Users/HP/Downloads/9781461471684-c1%20\(1\).pdf](file:///C:/Users/HP/Downloads/9781461471684-c1%20(1).pdf) (Last visited on 24.01.2018).

¹⁷ *Supra* note 13.

Various types of donors exist—unpaid relatives, unrelated altruistic donors, or sharing of oocytes as they undergo their own IVF treatment. Human organ donation in exchange for financial coercion is punishable by Indian legislation. Though this applies to kidney donation only, oocyte donation has not yet been included under legal purview. Whenever a child is born following either sperm donation or egg donation, the law requires that care should be taken of the newborn until he/she attains the age of “majority,” which is 18 years under India. Neglect of the offspring is not punishable, but when the husband and wife have signed the form of acceptance of oocyte donation in an IVF program, the courts have the power to compel the parents to take appropriate care of the child, until the child attains the age of 18 years.¹⁸ In USA, ASRM issues guidelines, but neither systematically monitors nor enforces them, and some of clinicians fail to follow these recommendations. For instance, ASRM recommends that donors be over 21 years of age, but over 40% of clinics appear to target younger women, who generally have better quality eggs, but may not have fully considered the long-term consequences of donation.¹⁹ The embryo donors must sign an informed consent document indicating their permission to use their embryos for donation, relinquishing all rights to the embryo(s) and any child or children that may result from the transfer of these embryos. They should be screened for genetic and infectious diseases to prevent transmission of these to the recipient or the offspring.²⁰ Many couple is choosing to put their unused embryos up for adoption. Several agencies across the United States arrange for frozen embryos to be given to other infertile couple. The adopted embryos are thawed and transferred into the uterus of the adoptive mother. This process eliminates the necessity for ovarian hyper stimulation of the adoptive mother and is cheaper than IVF.

Islamic law does not accept embryo adoption because procreation is only sanctioned between a man and a woman who are married. Because the man who donated the sperm is not married to the woman who will be the child’s mother, embryo adoption is not permissible. The objection to embryo adoption under Jewish law is that the adopted child may unknowingly marry

¹⁸ *Ibid.*

¹⁹ Keehn J, Holwell E, *et.al.*, “Recruiting egg donors online: an analysis of in vitro fertilization clinic and agency websites’ adherence to American Society for Reproductive Medicine guidelines” 98(4)*Fertil. Steril.* 995–1000(2012) cited in Robert Klitzman, Mark V. Sauer, “Creating and Selling Embryos for “Donation”: Ethical Challenges” 212(2) *Am J Obstet Gynecol.* 167–170(2015 February) available at: <https://www.ncbi.nlm.nih.gov/pubmed/25448512> (Last visited on 24.01.2018).

²⁰ *Supra* note 3.

his or her genetic sibling, resulting in incest.²¹ However, Catholic Church offers its respect and protection to the human being starting with its first seconds of existence; it considers the zygote, pre-embryo, embryo and fetus as persons and strongly disapproves research on embryos, cryopreservation and abortion. Hindu religion agrees with most of the assisted reproduction techniques, but it demands that the oocyte and the sperm used in the procedure to (better) come from a married couple. However, Hinduism also accepts sperm donation but the donor has to be a close relative of the infertile husband.²² Cryopreservation of pre-embryos may be permissible when it is to help the infertile couple and it serves the dharma of the physician. Buddhism is also a very liberal religion regarding assisted reproduction. It allows the use of IVF without restricting the access to this medical procedure to the married couples and sperm donation is also permitted. In the Buddhist tradition, a child conceived from donated genetic material has the right to meet his genetic parents as he reaches maturity.²³ Donation of sperm is not prohibited, but it is suggested to refrain from this procedure as much as possible. The oocyte donation can be practiced on the same grounds as sperm donation. They also accept cryopreservation of pre-embryos.

IV Ethical-Legal Issues

The practice of embryo freezing and donation raises many ethical issues, since it involves several parties with separate interests: the donor couple; the recipient couple; and the offspring. How strict should the criteria for selection of embryo donors be? Which couples should be offered embryo donation treatment? How old should the couples be that are treated? A further issue is whether to tell the child and others about the gamete donation, as the question of secrecy or disclosure affects both the donor and the recipient family.²⁴ The main ethical issues concern the effect on offspring, consent and counselling of donors and recipients, avoidance of mixing embryos or gametes from different sources, and payment of donor expenses. The main legal issues concern whether embryo donation is viewed as gamete donation or adoption; the rearing

²¹ Linda Bickerstaff, *Technology and Infertility: Assisted Reproduction and Modern Society* 48 (The Rosen Publishing Group, New York, 2009).

²² HN Sallam and NH Sallam, "Religious aspects of assisted reproduction" available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5096425/> (Last visited on 09.02.2018).

²³ Ying L Y, Har L, *et.al.*, "The experience of Chinese couples undergoing in vitro fertilization treatment: perception of the treatment process and partner support" Cited in HN Sallam and NH Sallam, "Religious aspects of assisted reproduction" available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5096425/> (Last visited on 09.02.2018).

²⁴ *Supra* note 8.

rights and duties of donors and recipients; liability; and compensation issues; and the legality of monetary compensation for donors. Use of embryos for research also raises serious issues.²⁵

1. Health Issues

Egg donors are hyper-ovulated to stimulate the production of a maximum number of eggs. Egg harvesting is done under anaesthesia—procedures that could pose health risks, including ovarian hyper stimulation syndrome.²⁶ Women donating oocytes must undergo IVF. Due to the inherent medical risks associated with IVF, including ovarian hyper stimulation syndrome and surgical risks, informed consent is another major issue of concern.²⁷ Additionally, it is considered an ethical prerequisite that oocyte donors participate voluntarily and without coercion or undue influence. Some have expressed concern that financial compensation of oocyte donors may lead to exploitation as women may proceed with oocyte donation against their own best interests, given the inherent medical risks involved. The “buying or selling” of human gametes is inherently immoral, as it lead to commodification of embryo.²⁸

2. Anonymity of donor

An issue of great controversy is whether children born using donated sperm should be able to know the identity of the sperm donor. Indeed, the ability of human beings to know their genetic roots is universally important, for the sake of self-identity. Either egg and sperm donors may choose to or not to be anonymous, though the vast majority in both groups generally chooses anonymity. Recently, however, there is, increasing consideration of the rights of offspring. Advocates for allowing either gamete donors or their offspring to break anonymity cite the medical advantages of sharing medical information with their genetic offspring, in the case of the donor, or learning about their genetic history directly, in the case of offspring. Others simply argue that both donors and offspring have an inherent right to meet and develop a relationship.

²⁵ Edward E.Wallach, John A. Robertson J.D, “Ethical and legal issues in human embryo donation” Volume 64 Issue 5 *Fertility and Sterility* 885-894 (November 1995) *available at*: <https://www.sciencedirect.com/science/article/pii/S0015028216578972> (Last visited on 24.01.2018).

²⁶ Jyotsna Agnihotri Gupta, “Reproductive Bio crossings: Indian egg donors and surrogates in the globalized fertility market”, Vol. 5 No. 1 *IJFAB* 25-51 (Spring2012) *available at*: <http://www.jstor.org/stable/10.2979/intjfemappbio.5.1.25>, (Last visited on 07-12-2017).

²⁷ *Supra* note 13.

²⁸ *Ibid.*

Recent court rulings suggest that these rights will become more visible in the coming future. For example, in the British case *Rose v Secretary of State for Health*²⁹, the court ruled that children born as a result of assisted reproduction had a right under Article 8 of the European Convention on Human Rights to discover information about their genetic parentage. However, a gamete donor who donated with the promise of anonymity also had a right under Article 8 to protect their anonymity.

The ethical and legal issues surrounding anonymity and gamete donation are sure to be a centrally debatable issues within the field of ART.³⁰ Children born using donated sperm have spoken of being incomplete without the full knowledge of their genetic origins. However it is not clear from research whether giving identifying information creates the feeling of completeness that these individual hope for.³¹

3. Surplus Embryos

IVF cycles often result in transferring several embryos and cryopreserving other embryos produced by the cycle, presumptively for the purpose of future pregnancy. However, in many instances, these surplus embryos are never used by the genetic parents and therefore are stored indefinitely. The number of such embryos stored internationally is surprisingly high. In the United States alone, it is estimated that over 400,000 embryos are currently cryopreserved, many of which will not be used by their genetic parents. The ethical and moral issues surrounding how to deal with these surplus embryos have been the source of much debate. In general, four possible fates for these embryos exist:(1)thawing and discarding,(2)donating to research,(3)indefinite storage,(4)donating the embryos to another couple for the purposes of uterine transfer.

A new study, by the Society for Assisted Reproductive Technology and the RAND Corporation, found that fertility clinics in the United State have nearly 400,000 frozen human embryos in storage—twice the highest previous estimate. The survey of 430 clinics showed that 88.2 percent of the embryos are being stored for possible future use. About 11,000 are set aside for scientific research. About 9,000 are designated for infertile couples. Another 9,000 will be

²⁹ [2002] EWHC 1593.

³⁰ Paul R. Brezina and Yulian Zhao, “The Ethical, Legal, and Social Issues Impacted by Modern Assisted Reproductive Technologies” 2012 *OGI* (2012) available at: <https://www.hindawi.com/journals/ogi/2012/686253/>(Last visited on 24.01.2018).

³¹ Jonathan Herring, *Medical Law and Ethics* 372 (Oxford University Press, New York, 2010).

thawed and destroyed.³² All of these strategies have staunch supporters and detractors. Not surprisingly, there are myriad laws in different countries governing many aspects of how a human embryo that has been cryopreserved may be handled. The use of embryos for the purpose of research, specifically as it relates to human stem cells, has also been a source of fierce debate internationally and has resulted in substantial regulation that varies substantially from nation to nation.³³

The disposition of unused embryos not only raises moral and ethical dilemmas for the couples who create them but also for society as a whole. To keep embryos for possible future use is not initially a controversial issue. It only becomes one when embryos have been frozen for several years and their viability or quality for transfer comes into question. How long an embryo can be frozen and still be safe to use in IVF is not known. The Catholic Church does not speak directly about the issue of discarding embryos because it considers ART, and all of its ramifications, to be unacceptable. The destruction of extra embryos is permissible by Jewish law if it is done passively by letting them thaw and die on their own. In most Protestant faiths, disposition of embryos is a personal concern of couple involved.³⁴

4. Payment for Embryo Donation

There has been debate over whether donors of gametes should be paid. In UK the HFEA does not prohibit the payment or giving of benefit in return for gametes, but it is only permitted if authorised by directions issued by the HFEA. However the EU Tissues and Cells Directive require that gametes should only be supplied on a non-for-profit basis. Art 12 of the Directive says that ‘donors may receive compensation which is strictly limited to making good the expenses and inconveniences related to the donation.’

Under the ART Guidelines of India the woman can be paid for her oocytes. Section 3.9.2 of ART Guidelines state:

Law Firms and semen banks will be encouraged to obtain (for example, through appropriate advertisement) and maintain information on possible oocyte donors and surrogate mothers as per details mentioned elsewhere in this document. The above organizations may appropriately charge the couple for providing an oocyte or a surrogate mother. The oocyte donor may be compensated suitably

³² Bob Smietana, “400K and counting” (JULY 1, 2003) *available at*: <http://www.christianitytoday.com/ct/2003/july/8.17.html> (Last visited on 24.01.2018).

³³ *Supra* note 28.

³⁴ *Supra* note 21 at 47.

(e.g. financially) by the law firm or semen bank when the oocyte is donated. However, negotiations between a couple and the surrogate mother must be conducted independently between them.

Thus the oocyte donor is paid for her donation. In USA, blue eyed, blonde-haired ivy league girls can sell their eggs for as much as \$50,000. The situation is no different in India, and websites advertise the “favourable” genetic characteristics of donors. Commerce and ethics are inextricably linked.³⁵ Women are selling their eggs for Rs 20,000-50,000, depending on their qualification and physical appearance. In India, freezing embryo costs Rs. 10,000 to Rs. 15,000 per month, and the frozen embryo transfer cycle costs Rs. 100,000 to Rs. 200,000 per cycle. Embryo transfer is the main part of the IVF process – and it usually takes 10 to 15 days to be injected in a woman’s womb.

5. Moral status of human embryo

The most important ethical question is the moral status of early embryo. Is it a person? Is it a thing? Or is it something in between? When during development is personhood established? In USA the Supreme Court held in 1973 in the case of *Roe v. Wade* that societal protection need not begin until viability, that is, late in pregnancy. In *Davis v. Davis* case, the lower court applied custody laws to the cryopreserved concepti, implying personhood at this early stage. However this view was reversed by the appellate court.³⁶ The court ruled that “pre-embryos” were neither persons nor property but entitled to “special respect” due to their capacity to become a person, relying on professional guidelines.

Biologically the human embryo is undoubtedly human; it has human chromosomes derived from human gametes. It is also undoubtedly alive - a new active individual human organism from the moment of fertilisation exhibiting respiration, growth, reproduction, excretion and nutrition. An embryo is a genetically distinct living human organism in itself, already with a unique genotype and the inherent ability to grow into an adult.³⁷ A human embryo is a whole living member of the species *Homo sapiens* in the earliest stage of his or her natural development. Unless denied a suitable environment, an embryonic human being will by directing

³⁵ Amit Sengupta, “the Commerce in Assisted Reproductive Technologies” in Sandhya Srinivasan (ed.) *Making Babies: Birth Markets and Assisted Reproductive Technologies in India* 53 (Zubaan, New Delhi, 2010).

³⁶ *Supra* note 7 at 20.

³⁷ Peter Saunders, The Moral Status of the Embryo, available at: <http://humanjourney.org.uk/articles/the-moral-status-of-the-embryo/> (Last visited 03.02.2018).

its own integral organic functioning develop himself or herself to the next more mature developmental stage, i.e., the fetal stage. The embryonic, fetal, infant, child, and adolescent stages are stages in the development of a determinate and enduring entity—a human being—who comes into existence as a single cell organism and develops, if all goes well, into adulthood many years later.³⁸

But while early embryos are much less developed than fetuses, they too are genetically unique, living human entities that have the potential to develop into full persons. The central problem in determining the legal status of early embryos is reconciling respect for human life and personhood with competing concerns of bodily integrity and procreative choice.³⁹ Neither an egg nor a sperm, by itself, can become a human being, while an embryo certainly does, and therefore, arguably, warrants special consideration. A purchased gamete contains only half of the future child's DNA, whereas the embryo contains the entire genome. Moreover, creating embryos raise questions related to quandaries of "when life begins" and when "an individual commences".⁴⁰

The pro-life position argues that a new person exists from the "moment" of conception or fertilization, because a new, genetically unique, living human being exists. Accordingly, the fertilized egg and early embryo may not be destroyed or aborted, and they deserve the rights and respect accorded persons. The opposing view agrees that the early embryo is genetically unique, living and human, with the potential to achieve personhood, but denies that those features and potential make the prenatal, living human entity itself a subject of rights or duties. Genetic uniqueness alone proves nothing if the cells in question lack other characteristics and hence lack interests.⁴¹ John Harris is of the view that there is no moral virtue in killing or allowing embryos to die when they could rather be used to benefit us all and there is less virtue in allowing human cadavers to go to waste, when we could, with, say, transplantation orders or the like, save very many lives.⁴² John A. Robertson stated that while the pre implantation embryo is clearly human

³⁸ Robert P. George, Alfonso Gómez-Lobo, "the Moral Status of the Human Embryo" Volume 48 Number 2 *Perspectives in Biology and Medicine* pp. 201-210 (Spring 2005).

³⁹ John A. Robertson, "In the Beginning: The Legal Status of Early Embryos" Vol. 76 No. 3 *Virginia Law Review* 437-517 (Apr., 1990) available at: <http://www.jstor.org/stable/1073266> (Last visited 08-12-2017).

⁴⁰ *Supra* note 8.

⁴¹ *Supra* note 37.

⁴² *Id* at 232.

and living, it does not follow that it is also a "human life" or "human being" in the crucial sense of a person with rights or interests.⁴³ There are three definitions given to the human embryo, such as: (1) The embryo is a human person, having an inalienable right to life; (2) The embryo is a heap of cells with the same moral status as the one of other cells and therefore, we behave toward it as it is a thing or a property; (3) The embryo is not a person, owner of rights, but it has to be protected as it is a potential person or a special entity.⁴⁴ The American Society of Reproductive Medicine has stated "The embryo deserves respect greater than that accorded to human tissue but not the respect accorded to actual persons. The embryo deserves respect than human tissue because of its potential to become a person and because of its symbolic meaning for many people. Yet, it should not be treated as a person, because it has not yet developed the features of personhood, is not yet established as developmentally individual, and may never realize its biological potential."⁴⁵

6. Potential Liability of Donor

What will be the situation of the AID child who suffers from a genetic defect passed on from the donor? Can the donor be found responsible for a failure to communicate his knowledge of the defect, or can the law find the donor negligent for a failure to discover the existence of the defect before becoming a donor, or the doctor in doing the treatment?⁴⁶ Under UK law, Section 1 of the Congenital Disabilities (Civil Liability) Act, 1976 provides that if a child is born disabled because of an occurrence which pre-dated birth, and someone is answerable for the existence of the disability, then that person can be found liable at the suit of the child. In a 2003 case, an egg donor tested positive as a carrier of the cystic fibrosis gene mutation, but the test result was not reported to the recipients, who proceeded with the egg donation process and went on to give birth to a child with the disease. The medical practice did not test the intended father for carrier status. While the court disallowed the child's claim for wrongful life, it permitted the parents to proceed with their malpractice case against the medical practice.⁴⁷

⁴³ John A. Robertson, "Resolving Disputes over Frozen Embryos" Vol. 19 No. 6 *The Hastings Center Report* 7-12 (Nov. - Dec. 1989) available at: <http://www.jstor.org/stable/3561979> (Last visited on 08-12-2017).

⁴⁴ *Supra* note 1.

⁴⁵ *Supra* note 14.

⁴⁶ Michael Davies, *Textbook on Medical Law* 243 (Oxford University Press, New York, 1998).

⁴⁷ *Paretta v. Med. Offi ces for Human Reproduction*, 760 N.Y.S.2d 639 (N.Y. Misc. 2003).

In India, the ART Guidelines state that a third-party donor and a surrogate mother must relinquish all parental rights in the child.⁴⁸

7. Embryo for Stem Cell Research

The use of frozen embryo in stem cell research has also created huge controversy. Until an embryo reaches the sixty-four-cell stage, cells of the embryo are capable of transforming themselves into any of the 220 types of cells in human body. Scientists are searching for ways to trigger stem cells to develop into specific types of cells. When specific triggers for each type of cell are found, it is hoped that new tissues can be grown to treat persons with diabetes, Parkinson's disease, Alzheimer's disease, and other conditions. This is the ultimate goal of the scientists doing stem cell research. Many people believe that this is a laudable goal but others disagree. When stem cell lines are created from frozen embryos, the embryos themselves are destroyed. For those who believe that life starts when an egg is fertilized, destroying embryos is a type of murder. For them, the use of frozen embryos for stem cell research is unacceptable.⁴⁹ Yet embryonic stem cell research is very controversial because the derivation of embryonic stem cells destroys the embryo. Thus, the morality of embryonic stem cell research depends primarily on the morality of destroying human embryos, raising the question of the moral status of the human embryo. Creating embryos for research treats the embryo as a mere object. Doing this 'may increasingly lead us to think of embryos generally as means to our ends rather than as ends in themselves'.⁵⁰ Studies say that embryonic stem cell has shown two major biological problems: first, contrary to the original hope, embryonic stem cells are rejected when transplanted into a genetically non-identical recipient. Thus the recipient would have to be treated to suppress the immune system. This treatment is very severe and currently associated with significant complications. Second, some of the animal data show that the differentiated

⁴⁸ National Guidelines for Accreditation, Supervision and Regulation of ART clinics in India, Para 3.5.5. Indian Council of Medical Research, National Academy of Medical Sciences (India), (2005), New Delhi: Ministry of Health and Family Welfare, Government of India.

⁴⁹ *Supra* note 21 at 50.

⁵⁰ Bonnie Steinbock, *The Oxford Handbook of Bioethics* 416-440 (Oxford University Press, 2007) available at: <http://famona.sezampro.rs/medifiles/oxford/oxford%20handbook%20of%20bioethics.pdf>. (Last visited on 24.01.2018).

embryonic stem cells are not entirely stable after transplantation. In particular, there have been some embryonic stem cells that develop into tumors.⁵¹

In Germany, the law bans the creation of embryos using the in-vitro fertilization (IVF) method for purely research purposes.⁵² In the United Kingdom, legislation has been enacted permitting the destruction of unclaimed embryos after five years.⁵³ In Europe and the US, stem cell research has become so controversial because it involves embryos. It is thus opposed by those who believe that life begins at conception.⁵⁴ Article 4 of the American Convention on Human Rights (ACHR) 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".⁵⁵ This mandate to protect life from the moment of conception is based on the understanding that the right to life exists from fertilization onwards. Otherwise, there would be no life to protect at that stage. Thus, the ACHR not only declares that unborn children have a right to life, but also that they are persons. 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."⁵⁶

The ninth paragraph of the Preamble of the Convention on the Rights of the Child also does so when quoting the Declaration of the Rights of the Child. It states: "the child, by reason of his physical and mental immaturity, needs special safeguards and care, including appropriate legal protection, before as well as after birth." Constitutions of some of the countries also protect life from the moment of conception.

India's stem cell research has been described as the next big thing to hit India after the country's software revolution. Embryos are already travelling from IVF clinics in India to public

⁵¹ *Supra* note 6 at 350.

⁵² Embryo Research: Regulation Dilemmas, *EPW* (December 1-8, 1990).

⁵³ Andrea D. Gurmankin, Dominic Sisti, *et.al.*, Embryo Disposal Practices in IVF Clinics in the United States, Vol. 22 No. 2 *PLS* pp. 4-8 (Sep., 2003) available at: <http://www.jstor.org/stable/4236705> (Last visited 14-12-2017).

⁵⁴ Sarah Sexton, "Emerging Genetic Technologies and Research: The Interlinkages with ARTs" in Sandhya Srinivasan(ed.) *Making Babies: Birth Markets and Assisted Reproductive Technologies in India* 66 (Zubaan, New Delhi, 2010).

⁵⁵ American Convention On Human Rights available at:

https://www.cartercenter.org/resources/pdfs/peace/democracy/des/amer_conv_human_rights.pdf (Last visited on 05.02.2018).

⁵⁶ The Baby Boy Case, United States, Case 2141, Inter-Am. Comm'n. H.R., Res. No. 23/81, OAS/Ser.L/VIII.52, doc. 48 (1981), available at: <http://www.cidh.org/annualrep/80.8leng/usa2141.htm>. (Last visited on 05.02.2018).

and private research laboratories trying to isolate stem cell both in India and elsewhere.⁵⁷ The ICMR in its ethical guidelines on assisted reproduction allows stem cell research with informed consent from the embryo donor and provided research begins within 14 days of embryo formation. But these guidelines are not binding; nor is there a monitoring and enforcement agency.⁵⁸

The mainstream Hindu view is that deliberate destruction of an embryo is homicide. The Vedas, the oldest of the sacred Hindu texts, emphasize the sanctity of life. The purpose of human life is to make progress towards this liberation from rebirth through. But the destruction of an embryo interrupts this process of reincarnation because according to traditional Hinduism, the soul is reborn from its previous life at the moment of conception. This means destroying an embryo means destroying a new life with a soul and this can interfere with progress towards liberation from rebirth. The Catholic Church, as well as Jewish law, does not sanction the use of frozen embryos for stem cell research because embryos are destroyed in the process. On the other hand, Islamic law allows the use of frozen embryos for stem cell research that is intended for therapeutic uses as long as prior consent of the couple who created the embryo is obtained.⁵⁹

V Embryo Disputes and Judicial Response

There is a lack of case law related to embryo freezing and donation in India. Only a few states in the U.S. have enacted statutes that provide for the disposition of frozen embryos. Left without statutory guidance, courts have struggled to determine whose interest shall prevail when disputes arise between couples as to the disposition of their unused embryos.

*Davis v. Davis*⁶⁰,

Mary Sue and junior Lewis Davis was a married couple who in the course of IVF treatment allowed seven of their embryos to be cryopreserved. The couples were not asked to give advance directions on what should be done with the embryos in the event of their marriage breaking up, and when this happened subsequently he did not wish to reproduce outside wedlock and wanted the embryos destroyed. Marry Sue, for her part, initially wanted an attempt to be

⁵⁷ *Supra* note 52 at 60.

⁵⁸ "Biomedical Research: Time to Get Our Act Together" *EPW* 3492 (September 15, 2001).

⁵⁹ *Supra* note 21 at 50.

⁶⁰ 842 S.W.2d 588 (Tenn. 1992).

made to implant them in her. However, by the time the case reached the Tennessee Supreme court she had changed her mind and wanted them to be given to another infertile couple.

The Tennessee Supreme Court decided that it must first categorize the human embryo. Rejecting suggestions that embryos are persons or property, the court found that they inhabit an interim category that entitles them to special respect because of their potential for human life. The court declared that any contract regarding the disposition of stored embryos should be presumed valid, binding, and enforceable. However, there was no such contract in the Davis case, the court engaged in a balancing test, where it weighed the interests of the parties against each other. The court determined that the essential question was whether the parties would become parents, thereby implicating their constitutional right to privacy and the related right to procreate or to avoid procreation. Despite the increased stress and discomfort that women undergo in the process of IVF, the court found that women and men must be seen as entirely equivalent gamete providers. Moreover, unlike with the question of abortion, the case did not involve interference with a woman's bodily integrity; therefore her interests would not automatically trump the man's. The court also found that the state's interest in the potential life embodied by the embryos was at best slight and not sufficient to justify any infringement upon individuals to make their own decisions about whether to allow the IVF procedure to continue. In this case, the couple divorced and the husband wanted to prevent the embryos from being implanted. The wife initially wanted to use the embryos herself, but by the time the case reached the state Supreme Court, she wanted to donate the embryos to a childless couple. The court determined that unwanted parenthood for the husband was a greater burden than the wife's knowledge that the IVF process would be rendered futile and the embryos she helped create would never become children. The court noted, however, that it would have been a closer case had the wife wanted to use the embryos herself. In that event, the court said, an additional factor to take into consideration would be whether she could achieve parenthood by other reasonable means, like adoption. Daughtrey J said:

To our way of thinking ,the most helpful discussion on this point is found not in the minuscule number of legal opinion that have involved frozen embryos but in the ethical standard set by the American fertility society, as follows:

Three major ethical positions have been articulated in the debate over pre embryo status. At one extreme is the view of the pre-embryo as a human subject after fertilization, which requires that it be accorded the right of a person. This position entails

an obligation to provide an opportunity for implantation to occur and tends to ban any action before transfer that might harm the pre-embryo research.

At the opposite extreme is the view that the pre-embryo has a status no different from any other human tissue. With the consent of those who have decision making authority over the pre-embryos, no limits should be imposed on action taken with pre-embryos.

A third view—one that is most widely held—takes an intermediate position between the other two. It holds that the pre-embryo deserves respect greater than that accorded to human tissue but not the respect accorded to actual person. The pre-embryo is due greater respect than other human tissue because of its potential to become a person and because of its symbolic meaning for many people. Yet, it should not be treated as a person, because it has not yet developed the features of personhood, is not yet established as developmentally individual. And may never realize its biological potential. In its report, the Ethics committee then calls upon those in charge of IVF programs to establish policies in keeping with the “special respect” due pre-embryos and suggests.

Within the limited set by institutional policies, decision making authority regarding pre-embryos should reside with the person who has provided the gametes. As a matter of law, it is reasonable to assume that the gamete providers have primary decision making authority regarding pre-embryos in the absence of specific legislation on the subject. A person's liberty to procreate or to avoid procreation is directly involving pre-embryos

We conclude that pre-embryos are not, strictly speaking, either “person” or “property”, but occupy an interim category that entitles them to special respect because of their potential for human life. It follows that any interest that Mary sue Davis and junior Davis have in the pre-embryos in this case is not true property interest. However, they do have an interest in the nature of ownership, to the extent that they have decision making authority concerning disposition of then pre-embryos, within the scope of policy set by law.

In the case of *Kass v. Kass*⁶¹, the highest court of New York held that agreements between couples regarding their unused frozen embryos should be enforced unless those agreements are contrary to public policy or unless the couple's circumstances have significantly changed. It further said that advance directives both minimize misunderstandings and maximize

⁶¹ 696 N.E.2d 174 (N.Y. 1998).

procreative liberty by reserving to the progenitors the authority to make what is in the first instance a quintessentially personal, private decision. The Supreme Courts of New Jersey and Iowa also concurred in saying that such contracts should be upheld, but subject to a large caveat: the right of either party to change his or her mind prior to the use or destruction of the embryos. This model, known as the “mutual consent” model, requires that both parties must contemporaneously agree in order for any action to be taken. According to the New Jersey court, when a couple disagrees as to the disposition of the embryos, the interests of both parties must be evaluated (effectively a balancing test). In Iowa, on the other hand, when the parties disagree, the status quo must be maintained until they can reach resolution or until the fertility clinic is no longer contractually bound to keep the embryos, with the expenses for maintaining the embryos to be shouldered by the party opposing their destruction. Although the courts have adopted a variety of tests to resolve such issues, thus far they have consistently ruled in favor of the spouse who opposes use of the embryos for procreative purposes. Massachusetts, New Jersey, and Iowa all based their reasoning in part on the fact that advance agreements to procreate or form other family relationships violate their states’ public policy and are unenforceable. Tennessee, in contrast, was reluctant to announce any bright-line rule and strained to point out that its holding should not be read to provide an automatic veto to a party seeking to avoid parenthood.

*In Roman v. Roman*⁶², the Texas Court of Appeals observed that there was an emerging majority view that written embryo agreements between embryo donors and fertility clinics to which all parties have consented are valid and enforceable so long as the parties have the opportunity to withdraw their consent to the terms of said agreement. The court also collected from a handful of Texas statutes that do address assisted reproduction that the public policy of the state would support this approach. What all of these courts have emphasized is that such disputes should be governed by existing statutes and that each case must be decided according to its own particular facts. On the one hand, it makes sense to require any person who contributes genetic material to an embryo with the intent to become a parent to designate, before hand, what should happen to that embryo if it is not used for its initial purpose. The process alone should help couples think through future scenarios and commit themselves to a particular course that may reduce the likelihood that a dispute will arise. To that end, further regulation may be helpful. On the other hand, it is in the clinics’ best interests to have patients fill out consent forms and it is likely that they now routinely collect information about what is to be done with unused

⁶² 193 S.W.3d 40 (Tex. App. 2006).

embryos, obviating the need for legislative mandates. As regards child custody disputes, fights over embryos in the U.S. can be incredibly fact sensitive. Suits of this nature will definitely benefit from legislative guidance which must reflect progressive values and will not violate or thwart constitutional protections.

VI CONCLUSION

To conclude, we see that on the one hand, the use of ART has revolutionized the life of humans, it fulfilled the hope of the despaired infertile people, made it possible for them to have their genetically linked child, but on the other hand the use of ART raised the number of social, ethical, moral, economic, religious, and health related issues which put a big question mark on the use of ART. Embryo freezing and donation also raised very serious issues which should be addressed by law. The guidelines formulated by ICMR are not binding and there is no monitoring agency. The law and policy should be formulated with the consultation with different stake holders. Following are the few suggestions that may be taken into consideration while drafting the policy:

1. The medical professionals dealing with ART are governed only by the norms of ethics and non-binding guidelines. The liabilities and responsibilities of medical and technical professionals are major issues which should be dealt by the specific legal norms and principles.
2. There are no standard treatment protocols for ART including embryo freezing and donation in India. Legitimate social issues that go beyond the exclusive expertise of doctors and scientists or market choice by patients need to be accommodated within the regulatory regime.
3. There is a need to make special provisions to ensure the welfare of children in the case of child born through embryo donation.
4. The social-ethical and religious norms should not be overlooked by undergoing the procedure of embryo freezing and donation.
5. There should be proper regulation of embryo freezing and donation in the context of stem cell research. Use of embryo for stem cell research should be strictly prohibited.
6. The rights as well as responsibility of the donor of embryo should be formulated by law.

7. Embryo freezing and donation generated moral-ethical dilemmas as well as legal disputes which involve status of embryo, cryopreservation, stem cell research, payment for donation etc. law and policies should be made to address these issues.
8. The commercial use of embryo should be prohibited through proper legislation. Sale and purchase of embryo should be made punishable under the law.