CHAPTER: III

In-vitro Fertilization and related technologies: Legal and Human rights issues

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IN-VITRO FERTILIZATION AND RELATED TECHNOLOGIES: LEGAL AND HUMAN RIGHTS ISSUES

Assisted reproductive technologies (ART) as artificial insemination, in-vitro fertilization, surrogacy, etc. have proved to be a blessing for many infertile couples. In western countries where many couples are facing infertility problem, assisted reproductive technology (ART) has been used quite frequently. Adoption laws in these countries are somewhat complex which renders to take services of these modern technologies and very difficult family laws of these countries are not ready to accept these technologies so easily. Artificial insemination and surrogacy raise various ethical and legal issues and the legislations in this regard are not uniform and vary from country to country influenced by their religious, political and social setup.

1. Meaning and Scope:

The medical science has made extraordinary advancement in the treatment of infertility. It has made it possible for couples, who would otherwise have not been able to procure children, to conceive and bear children. It has helped in fulfilling the desire of thousands of men and women to have their own children. The development of the technology is continuing process and it will go on and on, and it is because of these technologies that infertility is no more a cause of shame or something that has to be endured without attempted cure. Treatment of infertility may involve different technologies. These techniques, which are used to make a woman pregnant and to cure infertility, are grouped as Assisted Reproduction Technology (ART). So any “procedure or method designed to enhance fertility or to compensate infertility” outside the traditional means of procreation can be labeled as Assisted Reproduction Technology
ART. Similarly according to the 88th Report of the New Zealand Law Commission "a range of procedures designed to assist a couple or an individual to conceive a child with medical assistance" is called assisted human reproduction (AHR). According to this report, these "procedures may involve the use of donated sperm, eggs or a donated embryo to bring about conception." The whole process of achieving pregnancy may be fully or partially artificial. These processes provide the alternatives to bypass the natural process of intercourse between male and female.

Infertility treatment through Assisted Reproduction Technology (ART) is either by artificial insemination or by In-vitro fertilization (IVF). In recent years a new type of technology called "cloning" has developed. Though this technology is yet not used for the human reproduction but in future it may be used for human reproduction also. So with the development of this technology, scientists are demanding to group it with other Assisted Reproduction Technology (ART).

In-vitro fertilization (IVF) means fertilization occurring outside the human body, where eggs are fertilized with sperm in a laboratory, usually in a dish or test tube. For this reason, In-vitro fertilization (IVF) is also called test-tube conception. It is a medical procedure in which mature egg cells are removed from a woman, fertilized with male sperm outside the body and inserted into the uterus of the same or another woman for normal gestation. Here it is worth mention that this fertilization is called as in-vitro because it is done in a dish or test-tube of ‘glass’.

In-vitro fertilization (IVF) was originally developed to treat infertility caused by blocked or damaged fallopian tubes in the females. However, it is currently used to treat a variety of infertility problems. In the beginning of this

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2 Available at http://www.lawcom.govt.nz. (Last visited on 27/6/2013)
4 In Latin language “In-Vitro” means “in glass”.
technology its success rates were very low but at present due to inventions of many other assisting technologies its success rates have improved too much.\(^5\)

2. Procedural Techniques of In-vitro fertilization (IVF):

The In-vitro fertilization (IVF), involves collection of egg and sperm, and then placing them together in a test-tube or other laboratory dish to fertilize outside the body and then fertilized eggs when reach to eight cells stage embryo, which is also known as blastocyst, they are placed into the woman’s uterus.\(^6\) The whole process of In-vitro fertilization (IVF) is a four stage procedure:

- Ovarian Stimulation.
- Egg retrieval.
- Fertilization.
- Embryo transfer.

2.1 Ovarian Stimulation: To maximize the chance of fertilization with each In-vitro fertilization (IVF) attempt various hormonal medications are used, so that as many as possible ovarian follicles may be developed. These follicles are fluid filled in which eggs grow to maturity. Ovarian stimulation by hormonal medication is used to produce multiple mature follicles as only single egg normally develops each month. ‘Metrodin’ a hormonal drug of injectable class, which has to be given daily and a second hormonal drug called ‘Profasi’ is administered usually after the last dose of ‘Metrodin’. For this ovarian response is monitored by gynecologic ultrasonography and blood tests.\(^7\)

2.2 Egg retrieval: This is the next stage of In-vitro fertilization (IVF) cycle. The other hormonal drug ‘Profasi’ is administered after the last does of ‘Metrodin’. This drug would cause ovulation about 36 hours after this injection.

\(^5\) Available at http://www.mon/ezun.com/art.-3.htm (Last visited on 26/9/2013)
\(^6\) Supra note 3.
\(^7\) Ibid.
The eggs are retrieved just prior to that ovulation. There are two procedures commonly used: Laparoscopy and Ultrasound-Guided Aspiration.

In Laparoscopy procedure first a general anesthesia is given, then a tube with a tiny camera is inserted in the women’s part. This is done to enable physician to view the pelvic structure of ovaries and fallopian tubes. During that time an aspiration system is guided to ovarian follicles. This system retrieves the eggs and then placed in sterile test-tube.\(^8\)

Ultrasound-Guided Aspiration is the most common technique which involves a minor and safe surgical procedure general anesthesia. Here whole procedure is guided by ultrasound images, which allows for more accurate aspiration of the egg.\(^9\)

2.3 Fertilization: About 2 hours before the eggs are retrieved, a semen sample is collected from the male partner and the strongest and the most active egg is taken. If a donor sperm is to be used, the sample will then be taken from the freezer. Then eggs are placed into an incubator before it is mixed with the selected sperm.\(^10\) Between 20,000 to 30,000 sperms are mixed with each egg in a labeled dish. Then they are kept in the incubator for fertilization. It takes about 18 hours for fertilization. Where sperm count is low, intra-cytoplasmic sperm injection (ICSI) technology is used for fertilization.\(^11\)

2.4 Embryo Transfer: This is a simple procedure and can be performed without anesthesia. The procedure may be guided by ultrasound scan to check the position of the uterus.\(^12\)

3. Supplemental Techniques:

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\(^8\) Available at http://www.ivf-infertility.com/ivf/standard/procedure/egg.php (Last visited on 27/08/2013)
\(^9\) Ibid.
\(^11\) Ibid.
\(^12\) Supra note 5.
There are some other technologies also which may be used during In-vitro fertilization (IVF) process. These technologies are helpful in improving the success rate of In-vitro fertilization (IVF) attempts and the quality of this artificial procreative method.

3.1 Intracytoplasmic Sperm Injection: The procedure of Intracytoplasmic sperm injection was first used in 1992. In this procedure a single sperm is injected directly into the egg. It is used when there is low sperm count due to male infertility problems. This procedure is contrary to natural fertilization where sperms compete and when the first sperm enters the egg cell, the egg cell blocks the entry of any other sperm. Now scientists have developed a technique that allows selecting mature sperm.13

3.2 Zygote Intrafallopian Transfer: The process of zygote intrafallopian transfer is similar to the In-vitro fertilization (IVF) process. Here the zygote is transferred in the uterus of same women from whom the oocyte is retrieved. This is done to treat infertility due to fallopian tube blockage.14

3.3 Preimplantation Genetic Diagnosis: Preimplantation Genetic Diagnosis (PGD) refers to procedures which are performed on embryos prior to its transfer to uterus. By this process it is determined that the baby will be free from genetic deformity and disease or not. When Preimplantation Genetic Diagnosis (PGD) technology is used it is not to look for only identifying specific diseases, but also to identify embryos risk. This technology can be used for determination of sex also. Preimplantation Genetic Diagnosis (PGD) has replaced prenatal diagnosis, but it is expensive and complex process though it is done at preliminary stage of life from where there is a lot of scope to improve the genetics of embryo.15

13 Available at http://www.ivf-infertility.com/ivf/icsi.php (Last visited on 12/05/2012).
14 Available at http://www.ivf-infertility.com/gift/gift.5.php (Last visited on 12/05/2012).
15 Available at http://en.wikipedia.org/wiki/Preimplantation-genetic-diagnosis (Last visited on 10/01/2012)
3.4 Autologous Endometrial Co-culture: It is a possible treatment for the patients who have failed previous In-vitro fertilization (IVF) attempts or who have poor embryo quality. The patient’s fertilized eggs are placed on top of a layer of cells from the patient’s uterine lining, creating a more natural environment for embryo development.\(^{16}\)

3.5 Testicular Sperm Extraction: It is the process of removing a small portion of tissues from the testicle under local anesthesia to extracting the few viable sperm cells present in that tissue for the purpose. This process is recommended to men who are unable to produce sperm by ejaculation.\(^{17}\)

3.6 Gamete Donation: The process of In-vitro fertilization (IVF) requires sperm, eggs and a woman’s uterus to keep embryo till it develops into a baby. Since the 1980’s, women who could not benefit from In-vitro fertilization (IVF) because they were unable to produce healthy eggs on their own have been able to turn to another procedure called “egg donation”.\(^{18}\) Both sperm and ovum are the human cells necessary for sexual reproduction, they are also called gametes, sperm is male gamete and ovum is female gamete. So donor of sperm and ovum donor may also be called as ‘gamete donor’.

3.7 Surrogacy: In-vitro fertilization (IVF) in its last step requires transfer of embryo into the uterus of women, that uterus may be of female partner of couple who are to be treated for infertility or of any third women. This practice whereby one woman carries a child for another woman with the intention that the child should be handed over after birth to the women is called surrogacy.\(^{19}\) At last stage of In-vitro fertilization (IVF), the embryo’s transferred to the uterus of surrogate women. It is used when the female partner of intending parents is not able to bear children. In the 21st century, In-vitro fertilization

\(^{16}\) Available at http://en.wikipedia.org/wiki/Assisted-reproduction-technology#Expansion-of-IVF (Last visited on 12/03/2012)

\(^{17}\) Available at http://www.malereproduction.com/12-spermaspiration.html (Last visited on 20/02/2008).

\(^{18}\) Supra note 1, p. 74.

\(^{19}\) Supra note 1, p. 75. Note: “Surrogacy” has its origin from word “Surrogate” meaning substitute.
(IVF) has much developed and so on the form of surrogacy has been changed as it is now commercialized. Surrogacy contains several controversial issues and has been dealt in detail in the next chapter.

4. Artificial Insemination:

Artificial insemination is the insertion of sperm into a woman's vagina to cause pregnancy using a method other than sexual intercourse. Women with infertile husbands; single woman and lesbian couples often resort artificial insemination in order to become pregnant. Where the male genetic material of the husband is introduced artificially into women's body, it is known as "Artificial insemination Husband" (AIH). Where the genetic material is obtained from a male other than the woman's husband, it is called Artificial Insemination Donor (AID).

So for as Artificial insemination Husband (AIH) is concerned, legal problem are not significant. The process is artificial, but substance injected is one that does not deviate from the ordinary norms of marriage. As far as legal problems are concerned, the major one relates to the legitimacy of the child born. A marriage is actually said to be consummated only when the parties have sexual intercourse with full or at least partial penetration after solemnization. However, if a wife is inseminated artificially with the husband's sperm and gives birth to a child, does the conception or birth of the child constitute consummation of marriage? But Artificial insemination by donor (AID) has several legal issues. The issue whether artificial insemination amounted to consummation or not was raised in Slater v. Slater. In this case Artificial insemination by donor (AID) was resorted but was unsuccessful and ultimately, a child was adopted. It was

22 Probate Division, 235, 1953.
held that the attempted insemination could not constitute consummation and that the doctrine of approvation could not be applied to defeat the wife's claim despite insemination and adoption.²³

In India the question whether artificial insemination amounts to consummation for marriage can be answered according to personal laws. Under Section 32 (a) of the *Parsi Marriage Act, 1936* non-consummation within one year of marriage is a ground for divorce. On the same ground with no specific limit, either party can sue for a decree of annulment of marriage under Section 25(1) of *Special Marriage Act, 1955*. The wife can seek annulment of marriage on its non-consummation due to the impotency of the husband.²⁴

### 4.1 Issues relating to artificial insemination:

#### 4.1.1 Adultery and cruelty:

If the impregnation is by another male with the husband's consent, there will be no charge of adultery or cruelty. But where the husband has not given consent, then the conduct is likely be regarded as an act of cruelty for the purposes of law of divorce. Where such conduct becomes adultery is however, doubtful. In the Scottish case of *MacLennan v. MacLennan*,²⁵ after much debate, it was held that there would be no "adultery" in the legal sense, by a woman getting herself artificially inseminated without her husband's consent, as there in no sexual contact between woman and the donor. The same view is likely to be taken in India because the *Indian Penal Code* also lay stress on the physical element. Moreover, the code specifically provides that the woman shall not be punished for adultery in any case.²⁶ Even under the *Hindu Marriage Act, 1955* in the absence of any special definition, adultery means consensual sexual intercourse between married person and another person of the opposite sex during the subsistence of a valid marriage.

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²³ *Supra note* 21, p. 46.
²⁴ *Id.*, p. 47.
²⁵ *(1958) SC 105*
²⁶ *Supra note* 20, p. 32.
4.1.2 Legitimacy of the Child: The Artificial insemination by donor (AID) child is procreated with the use of the semen of a third person therefore the donor presumably will be the real father of the child and the child will thus be deemed as bastard child. In United States the legislations and in the juristic opinions the child is legitimate when the husband expressly or impliedly had consented for insemination.\textsuperscript{27} English law has presumption about the consent and parentage. The Law Commission in its report suggested that where there was consent of husband for insemination, the child should not be deemed of the donor. The recommendations of the Law Commission was partly adopted in the \textit{Family Law Reform Act, 1987}, whereby it will be deemed that there is consent of the father and the child will be deemed to be of the spouses. But this presumption is rebuttable through the court of law.\textsuperscript{28}

In India there is no statutory law to determine the legitimacy and the parentage of the Artificial insemination by donor (AID) child during the subsistence of the marriage will be deemed the legally wedded spouses. \textit{Muslim Hanifi Law} says that child taking birth not within six months of the solemnization marriage and after two year of the repudiation of marriage or death of the husband will not belong to the husband. There is a strong presumption about the parentage of the child. There is also provision for acknowledgement by the father about the legitimacy of the child. But the law does not have provisions for legitimating. When the children are proved to be illegitimate, law does not provide legitimacy to them. Therefore the law provides that the above mentioned presumption is rebuttable. The grounds for rebuttableness can be impotency, sterility and non-access.\textsuperscript{29} In case of Artificial insemination by donor (AID) there cannot be any presumption, as it would be evident from the facts that the natural father of the child is the donor therefore the Artificial insemination by donor (AID) child will be illegitimate.

\textsuperscript{27} A.H Ansari, “Artificial Insemination: Indian Perspective”, \textit{Ban. L.J}, 1991-92, p.71
\textsuperscript{28} \textit{Ibid}.
\textsuperscript{29} \textit{Id.}, p. 72.
The *Indian Evidence Act*\(^\text{30}\) also provides for similar presumption where the child would be legitimate child of the woman and her husband and the artificiality of the process would make no difference. According to it the child born during the continuance of a valid marriage or within 280 days after the dissolution of marriage shall be conclusive proof that the child is of the husband.

In the light of the existing law, however, if the facts of Artificial insemination by donor (AID) are not known due to extreme secrecy, the child would get the protection of the above provisions. But in absence of such secrecy the child will be illegitimate. Therefore, the legitimacy can be granted to such children only by legislation.\(^\text{31}\)

### 4.1.3 Anonymity of the Gamete Donor:

In England the *Human Fertilization and Embryology Act, 1990* stipulates that gamete donation should be anonymous; the identity of the donor cannot be given to either the donor offspring or the couple receiving the gametes. Internationally, the vast majority of the countries endorse anonymous gamete donation and some countries such as France, Denmark and Norway do not allow offspring’s related any information. There does; however in recent years seem to be a discernible trend towards allowing children access, to identify information about their gamete donor. The first country to remove the anonymity of gamete donors was Sweden in the year 1984. *Law No. 1140* allowed the child, when sufficiently mature; to find out the identity if there was any sperm donor. Austria also allows the child to gain identifying information following the passage of federal legislation on medically assisted procreation by *Law No. 275, 1992.*\(^\text{32}\)

In the United States there is no legislation, at either federal or state level, that either prohibits or permits anonymous gamete donation. The matter is

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\(^{30}\) *Indian Evidence Act*, Section 112.

\(^{31}\) Supra note 27, p. 73.

regulated by non-legally binding professional guidelines, which recommend the anonymity of gamete donors. There are, however, sperm banks that have begun to offer a known donor service. The Rainbow Flag Clinic in California, for example, offer an exclusively known service, while other clinics such as the Sperm Bank of California, have started to offer anonymous and non-anonymous sperm donation in which both the donor and the couple can choose which type of donation they wish to have.\textsuperscript{33}

\subsection{4.1.4 The Child right to know and parent's right not to tell the genetic origin:} Many societies in the present time have begun to place greater emphases on children's right. Article 7 of the \textit{United Nations Convention on the rights of the Child, 1989} can be seen as being of fundamental importance which provides the right to know one's parents. In the context of donor anonymity it has been expressed as the child's right to know the identity of their gamete donor. In our contemporary culture young people have strong moral claims to know the genetic identities. It has been contended by some that now it is time for these moral claims to convert to legal rights. Such a right-based argument has been used by various legislatures to justify policies of non-anonymous gamete donation.

Whether or not the child is harmed by not knowing their biological origins, it has been argued that donor offspring's have a right to the truth, about their conceptions and origins. At present, as the law stands donor offspring's are the only group in Britain specifically denied the right to know the identity of their biological parents.\textsuperscript{34}

Family therapy practitioners claims that openness and honesty are to be preferred and basing family life on deception and secrecy can cause stress and anxiety within the family. In this respect, \textit{Warnock} has said, "I cannot argue that children who are told of their origins, if they are Artificial insemination by

\textsuperscript{33} Ibid.

\textsuperscript{34} Mc Hale J. and Fox M., Health Care Law text and materials, Sweet and Maxwell, London, 1997.
donor (AID) children are necessarily happier or better off in any way that can be estimated. But I do believe that if they are not told they are being wrongly treated.\textsuperscript{35}

There are some people who argue that in case of gamete donation there are compelling reasons for not telling the child. It has been contended that it is not in the best interest of the child to tell about the gamete donation because there is a fear that telling the donor child how they are conceived would cause severe social and psychological problem. There is also a concern amongst recipient couples to protect the male partner from the stigma of infertility and a fear that if the child was told that he was not the biological father, the relationship between the two might suffer.

A further reason for not telling the child is that parents should have a right to privacy and if they wish to keep such information confidential that is their prerogative. It is clear that balancing of these competing interests is a difficult matter and requires a full debate discussing the merit of each case. So far as the non-anonymous gamete donation is concerned the practical argument against it is that introducing a system of known donors would seriously reduce the number of potential donors and is so doing jeopardize the whole programmed of artificial insemination. In future it might well be the choice to be made between a reduced, non-anonymous programme that respect the child's right to know and a much wide anonymous programme that seek to benefit a greater number of childless couples.\textsuperscript{36}

5. In-vitro Fertilization (IVF) and Ethical & Legal Issues:

These technologies have raised many ethical and legal issues which must be answered by a legal system. Issue may arise as to accessibility of In-vitro Fertilization (IVF) i.e., as to eligibility to access this technology. Similarly

\textsuperscript{35} Supra note 32, p. 821.
\textsuperscript{36} Supra note 32, p. 823.
where donated gametes are used, issue as to eligibility of donor and donee of
gametes may also arise. In case of preserved embryos questions as to the legal
status of embryo, nature of right on embryo may arise. This is a challenge to the
present legal system. The most important issue in the case of the use of donated
gametes may arise as to the parentage and inheritance of children conceived
through In-vitro Fertilization (IVF) by using those donated gametes. Apart from
above mentioned technologies there are several other legal and ethical issues
which require answer from our legal system.

With the development of these technologies and its commercialization
the complexity of legal questions raised by the In-vitro Fertilization (IVF) are
increasing day by day. In country like India where there are different personal
laws for different religious groups, the need to address these issues through a
proper legislation is more prominent.

5.1 Eligibility to In-vitro Fertilization (IVF): If gay couples and single person
(i.e. unmarried male or female) are approaching to In-vitro Fertilization (IVF)
clinics, ethical and legal question arise as to who should be allowed to have
children with the help of In-vitro Fertilization (IVF). Should only married and
infertile couples be allowed or every individual was free to approach these
clinics and to have a baby?

Originally these technologies were developed to help infertile married
couples. But today these technologies are used by persons who are not suffering
from infertility problems, but are simply desirous to have children who were
genetically related to them, which they cannot have through adoption. These
technologies also give an option to a woman (single or married) who desires to
have their own genetic children without labour pain, and can opt for In-vitro
Fertilization (IVF) with surrogacy. Same is the reason with gay, lesbian and
single men to avail themselves of these reproductive technologies. But to

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prohibit these persons from taking help of In-vitro Fertilization (IVF) would mean to deny them the joy of having children genetically related. This would be a violation of basic human right to form family. It will also be violation of constitutional right to procreate in some countries. As far as the welfare of child is concern the users of such technology intends to produce a child and intend to accept the responsibility of caring for it. Intent to create and care for a child, acted upon through artificial procreation, is a positive intent that should be protected by law.\textsuperscript{38}

Those who oppose right of single parents, lesbians, gays to avail themselves of these technologies, they argue that for the child’s complete development fathers care and mothers love both are necessary and they will not get it in case of single parent or lesbian couples. They argue that if we allow it then the changing family structure would hamper the interest of child. If those arguments are accepted then it would mean that they are being compelled to marry with opposite sex just for procreating a child of their own gene. Who know how stable such marriages would be, and how helpful that family atmosphere would be for these children? No doubt it is in the interest of children to be brought up in a stable, friendly and traditional family setting of two parents, but it does not mean that gay or lesbian or straight single men has no sufficient sense of responsibility. Family structure in itself is not predictive of parenting quality, and it is an inadequate proxy measures for child outcomes due to the huge variation in levels of functioning within any one family form.

The Chief Commissioner, Families Commission of New Zealand has held that “Children are better off with two parents committed to each other. We don’t dispute that. But there are a good number of two parent families making a

mess of it and there are a number of single parent families doing exceptionally well. Whatever the family is, it needs to be supported.”

In India when adoption is allowed for single parent (whether male or female), thus avoiding the need of both parents (father and mother) it is submitted that opposition of single parenting with the help of In-vitro Fertilization (IVF) is not tenable. Parenthood through the In-vitro Fertilization (IVF) is planned for years and the implications of becoming a parent have been thought for long before conception.

5.1.1 Laws in Developed Countries:

5.1.1.1 United States: In the US, there is no federal regulation of Assisted Reproduction Technology (ART). Different states have different legislation to regulate Assisted Reproduction Technology (ART). Nearly 33 states have enacted statutes to regulate Assisted Reproduction Technology (ART). Only the state of New Hampshire explicitly restricts access to artificial conception procedures. Under New Hampshire law, In-vitro Fertilization (IVF) and pre-embryo transfer are available only to a woman who is aged 21 years or over and who has been medically evaluated and received counseling. In the remaining jurisdictions none of the relevant statutes expressly prohibits access to Assisted Reproduction Technology (ART) by single women. However, some states imply that only married women will employ Assisted Reproduction Technology (ART). Others implicitly recognize that unmarried women may access Assisted Reproduction Technology (ART), but they do not have any express provisions. In Jhordan C. v. Mary K., the California Court of Appeal held that the word ‘Woman’ in California family Code includes unmarried women.

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40 Hindu Adoption And Maintenance Act, 1956; Sec. 7 and 8.
41 Available at http://www.law.reform.vic.gov.au/ (Last visited on 29/08/2012)
42 224 California Reporter 530, 1986.
5.1.1.2 Canada: In Canada there is the Assisted Human Reproduction Act, 2004. This Act establishes under Sec. 2(1) the Assisted Human Reproduction Agency to protect and promote the health and safety, and human dignity and also to foster the application of ethical principles related to Assisted Human Reproduction. Sec. 2(a) of the Act provides that “the health and well being of children born through the application of assisted human reproduction technologies must be given priority in all decisions respecting their use.” According to Sec. 2(b) “the benefits of Assisted Human Reproductive Technologies and related research for individuals, for families and for society in general can be most effectively secured by taking appropriate measures for the protection and promotion of human health, safety, dignity and rights in the use of these technologies and in related research.” It is also provided under Sec. 2(e) that “the persons who seek to undergo assisted reproduction proceeded that must not be discriminated against, including on the basis of their sexual orientation or marital status.” Thus, it is clear from Sec. 2(b) and 2(e) that single parent or lesbian or person of any sexual orientation may seek help of Assisted Reproduction Technology (ART). But Sec. 2(a) empowers authorities to deny Assisted Reproduction Technology (ART) to those who are considered likely to prove unsuitable parents.

5.1.1.3 Australia: In Australia, the power to legislate on the subject of Assisted Reproduction Technology (ART) is not with the Common Wealth of Australia, it is with the States. Only three states, i.e. Victoria, Western Australia and South Australia have done so. The majority of the other States and territories adhere to ethical guidelines formulated by the National Health and Medical Research Council (NHMRC) and the Fertility Society of Australia. In Western Australia, there is Human Reproductive Technology Act, 1991. This Act has also established the Western Australian Reproduction Technology Council.
According to Sec. 23 of the Act, In-vitro Fertilization (IVF) procedure may be carried out where it would likely to benefit:

- persons who, as a couple, are unable to conceive a child due to medical reasons;
- a woman who is unable to conceive a child due to medical reasons, or
- a couple or a woman whose child would otherwise be likely to be affected by a genetic abnormality or disease.

Thus, the *Human Reproductive Technology Act, 1991* does not permit male single parent to have child through In-vitro Fertilization (IVF) and gestational surrogacy, though women are permitted to use In-vitro Fertilization (IVF) and other Assisted Reproduction Technology (ART).

In South Australia, there is *Reproductive Technology (Clinical Practice) Act, 1988*. This Act has established the South Australian Council on Reproductive Technology, which is empowered to formulate a code of ethical practice to govern the use of artificial fertilization procedure. Sec. 13(3)(b) of the Act provides that the licensees under the Act may provide artificial fertilization procedure only for the benefit of married couples in the following circumstances:

- the husband or wife (or both) appear to be infertile; or
- there appears to be a risk that a genetic defect would be transmitted to a child conceived naturally.

Thus, the married couples under Sec. 13(3)(b) of the Act may be of the same sex (i.e. lesbian or gay). But no single men or women is allowed to have Assisted Reproduction Technology (ART) treatment. In 1996, the South Australian Supreme Court in *Pearce vs. South Australian Health Commission*[^45^](#fn)

held that the restriction of access to treatment on the basis of marital status violates the *Sex Discrimination Act, 1984*. So now single women and couples who do not meet the criteria of the Act as to marital status may now access to Assisted Reproduction Technology (ART) treatment.

In Victoria, there is the *Infertility Treatment Act, 1995* which regulates the use of Assisted Reproduction Technology (ART). It has established the *Infertility Treatment Authority* which administers the licensing and approval systems with respect to ‘treatment procedures’. Assisted Reproduction Technology (ART) procedure may be performed only by approved doctors at licensed hospitals or day procedure centers or licensed research institutes. Sec. 8 of the Act defines the eligibility criteria. According to it, “a woman who undergoes a treatment procedure must be married or living with a man in a de-facto relationship. Both she and her husband must consent to the procedure. It must be established that the woman is, unlikely to become pregnant or that she or her spouse is likely to pass on a genetic abnormality or disease to a person born to them without the assistance of Assisted Reproduction Technology (ART).” Sec. 20 of the Act prevents a woman from undergoing a treatment procedure involving the use of donor sperm, or an embryo formed from her ovum and donor sperm, unless the woman is unlikely to become pregnant from the sperm of her husband or a genetic abnormality or disease might be transmitted as result of using his sperm. It also prevents from the use of embryo formed by using donated ovum and husband’s sperm unless she is not able to become pregnant by using her own ovum or such pregnancy would transmit genetic abnormality or disease to resulting child. It also prevents the use of both donated gametes unless any of the above mentioned reasons are present.46 Thus, single men or women were not allowed to approach Assisted Reproduction Technology (ART) clinics in Victoria. But now *Infertility Treatment Authority*  

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has accepted that a single woman can access to Assisted Reproduction Technology (ART) services.

5.1.1.4 United Kingdom: In United Kingdom, there is Human Fertilization and Embryology Act, 1990. This Act establishes the Human Fertilization and Embryology Authority which issues license and maintains code of practice of Assisted Reproduction Technology (ART) service provider. According to Sec. 13(5) of the Act, a woman shall not be provided with treatment services unless account has been taken of the welfare of any child who may be born as a result of treatment (including the need of that child for a father), and of any other child who may be affected by the birth. According to Sec. 13(6), “A woman shall not be provided with any treatment services involving:

- the use of any gametes of any person, if that person’s consent is required;
- the use of any embryo the creation of which was brought about in vitro; or
- the use of any embryo taken from a woman, if the consent of that woman is required.

These provisions have given effect to the Warnock Committee Report which observed that “we believe as a general rule, it is better for children to be born into a two parent family, with both father and mother”.47

On the basis of these legislative frameworks of different countries, it can be observed that Assisted Reproduction Technology (ART) can be generally accessed only by married couples. But with the help of court, the right to access Assisted Reproduction Technology (ART) has extended to a woman who is not married.

5.1.1.5 Position in India:

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In India, there is no statute to regulate Assisted Reproduction Technology (ART) services. So, everyone is free in this country to access Assisted Reproduction Technology (ART) services. We have only guidelines of Indian Council of Medical Research (ICMR) to supervise and regulate Assisted Reproduction Technology (ART) clinics. As these guidelines do not have any statutory force, they are not enforceable but have only recommendatory effect. Section 3.52 of the Indian Council of Medical Research (ICMR) guideline enumerates that “there would be no bar to the use of Assisted Reproduction Technology (ART) by a single woman who wishes to have a child, and no Assisted Reproduction Technology (ART) clinic may refuse to offer its services to the above, provided other criteria mentioned in this document are satisfied. The child thus born will have all the legal rights on the woman or the man”. Thus it has allowed the access for single women to Assisted Reproduction Technology (ART) services.

There is no provision in the Indian Council of Medical Research (ICMR) guidelines which expressly deal with single male to access Assisted Reproduction Technology (ART) services. It has not dealt with the question whether a single parent who is male, can use Assisted Reproduction Technology (ART) with the help of Surrogacy to have his own genetic child. He would not be able to get his own genetic child through adoption which is his legal right to adopt. It is submitted that a single male should be allowed to have a child through surrogacy and other Assisted Reproduction Technology (ART) services.

5.2 Issues related to Gamete Donation: In In-Vitro Fertilization (IVF) one can use the donated or purchased gamete. So question arises that whether we should allow selling or purchasing of gamete or not? In India and several other countries, there is no answer to this question in statute books. Whether a person  

48 National Guidelines for Accreditation, Supervision and Regulation of ART Clinics in India, Available at http://www.icmr.nic.in/art/clinics.htm (Last visited on 17/09/2012)
has property interest on one’s gametes or not? This question does not find answer in statutes which deals with individuals control over their bodies. But it is understood by the common man that there is a sort of interest of a person in his gamete, which allows him to donate it. The donors therefore believed to have discretion to dispose of their gametes according to the medical and ethical norms. When we donate gametes then what sort of right we transfer to donee? Whether it is the ownership and property claims or simply reproductive autonomy and parental claims over any offspring resulting from those gametes?

As far as selling of gametes is concerned, if selling or purchasing of gametes is allowed then a questions arises whether it would not be against the dignity of human life? Fertility clinics in countries like the UK, US, Israel, Australia, Spain, Denmark and many other countries are now turning to India in search of ovum. India is now becoming centre for biological process outsourcing. This is because those who donate ovum are getting some amount of money from those who are in need of ova.49 This programme is getting popularity as in India; there is no law to regulate Assisted Reproduction Technology (ART) clinics and to prohibit selling or purchasing of gametes. In UK, Canada and Australia gametes selling and purchasing is prohibited but compensation in lieu of the donors services are permitted.50 In India, the Indian Council of Medical Research (ICMR) guideline provides that the donors of gametes may be appropriately compensated.51 It is submitted that the provision relating to financial compensation for service of donor is good as in absence of it there may be non-availability but selling and purchasing of gametes must be prohibited as it is against the dignity of human life. The Indian Council of

49 Available at http://timesofindia.indiatimes.com/cms.dll/htm/uncomp/articeleshow (Last visited on 2/7/2013)
51 Supra note 48, Section 3.91 and 3.92.
Medical Research (ICMR) has also recommended for prohibition on sale and purchase of gametes and embryo.52

Other questions also arise, as, who can donate gametes? Whether everyone should be free to donate gametes to any one or should there be some criteria to decide as to who can donate to whom? Whether there should be medical screening of donors before donation or not? One potential donor of a particular area can donate to how many couples? Whether incestuous relations rule of marriage laws be followed in gamete donation also or not?

There are different personal laws based on religions in India. These personal laws prohibit marriage in certain relations. These relations are incestuous relations and donation of gamete to a couple with whom a person cannot marry, raises a controversial issue before our law framers, which must be answered. As far as Indian Council of Medical Research (ICMR) guidelines are concerned it totally prohibits gamete donations by a relative or a friend of the couple seeking treatment.53

It is submitted that total prohibition is not correct and donation of gametes only by person with whom the couple cannot marry should be prohibited. Medical screening of the donor of gamete should also be made compulsory. Use of gametes donated by a potential donor for patient of a particular area must be regulated and it should be restricted to appropriate number of patients. Rights and duties of gamete donors must be fixed by the statute to avoid future controversies.

5.2.1 Duties of Donor: The donor of gamete must be liable to fulfill following duties:
to inform physician as well as recipient if possible, details known to him about his/her genetic abnormalities, or of the person to whom he is genetically related;

to voluntarily submit himself or herself for medical screening before the donation of the gametes;

to surrender all his rights in gametes to the recipient or the gamete bank as the case may be, he/she should also surrender his rights in relation to child conceived as a result of use of his gamete;

not to make any attempt to gain knowledge about the identity of the recipients or their child; and

to get consent of his/her spouse (in case of married donor) for such donation, as in case of absence of consent it may amount to an injury to other spouse, in gamete donation by a married person, such a requirement has to be made while signing the consent form in order to protect marital ties.\(^54\)

5.2.2 Rights of Donor: Along with duties, donor should be given following rights:

the assurance of his identity and other information regarding him which may harm him shall not be allowed to pass on to the recipient as well as the child born with the help of his gamete. This provision may conflict with the children's right to know his genetic lineage. A balance has to be set up and children right should be allowed to override the right of the donor only in necessary conditions; and

to get assurance as to absence of his liabilities towards the child born by using his gametes. He must be given right to not bear the parental

5.3 Parentage and related issues:

Legitimacy of the child decides the parentage of the child and parentage decides the responsibility of care, protection and maintenance of the child. Parentage also decides the inheritance. A person generally inherits the property of his parents. Inheritance of property was the reason behind to evolve the institution of marriage. This was evolved to ascertain the parentage of the child born for the purpose of inheritance. Because of this reason, it becomes of utmost important to discuss the parentage of child conceived and born with the help of In-Vitro Fertilization (IVF). Before invent of these technologies, there was no technical problem in deciding the parentage. The women from whose womb child takes birth was considered mother and her husband his father. But now with the help of In-Vitro Fertilization (IVF) it is possible that woman who give birth to the child and her husband may not have any genetic connection with that child.

When a child is born through In-Vitro Fertilization (IVF) it is believed that if the genetic material is contributed by the husband and the wife the child would be legitimate. This is when the contributors of the genetic materials are lawfully married. The fact that the fertilization was in a test tube would not matter. But when the commissioning person is a single women or a man who has taken the help of gestational surrogacy, then the issue becomes complicated. It is also complicated when one of both gametes is of other than commissioning couple or they have taken embryo in donation. Problem as to parentage of child conceived through In-Vitro Fertilization (IVF) arises when a question as to custody and maintenance reaches to court and court orders for Deoxiribo

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Nucleic Acid (DNA) testing. As Deoxiribo Nucleic Acid (DNA) test reveals the genetic parent so it makes the status of social parents controversial.

There is no law in India to confer legitimacy on the child and to treat the child as legitimate child of commissioning mother and her partner or single mother. So such types of parents only have help of contract between donor of gametes or embryo and the commissioning person i.e. the donee.

In Australia, different states have different law as to parentage of Assisted Reproduction Technology (ART) born child. In Western Australia where a woman uses a donated ovum, she is the mother of any child born as a result of the pregnancy. Where a married woman undergoes, with the content of her husband an artificial fertilization procedure, the husband is the father of any child born from it. Where a woman who is in a de-facto relationship with another (whether of same sex or opposite sex) and woman undergoes with the consent of her partner an artificial fertilization procedure, the de-facto partner of the pregnant woman is conclusively presumed to be a parent of the unborn child and is parent of any child born as a result of the pregnancy. Where a woman becomes pregnant in consequence of an artificial fertilizations procedure using a donated ovum, the donor is not the mother of the child and when donated sperm is used, the donor is presumed not to have caused the pregnancy and is not the father of the child. Similarly in South Australia also where a woman becomes pregnant in consequence of a fertilization procedure using donated ova or sperm, the donor is not a parent of the resulting child. Unlike the Western Australian Counterpart, the Family Relationship Act, 1975 does not include a provision for parentage applying to same sex couples. In those Australian Jurisdictions where there are no statutes regulating Assisted Reproduction

56 Artificial Conception Act, 1985, Section 5.
57 Ibid, Section 6(1)(a)(b).
58 Ibid, Section 6A(1)(a)(b).
59 Ibid, Section 7.
60 Family Relationship Act, 1975, Sec. 10C.
Technology (ART), there are laws relating to the parentage of children conceived as a result of fertilization procedure. They provide as under:

- where a married woman or a woman in de-facto relationship becomes pregnant as a result of a fertilization procedure she is presumed to be the mother and her husband, provided he consented to the procedure, is presumed to be the father;
- where a woman becomes pregnant by means of a fertilization procedure using sperm obtained from a man who is not her husband, the donor is presumed not to be the father; or
- where a woman becomes pregnant by means of a fertilization procedure using another woman’s ovum, the donor is presumed not to be the mother.61

In Canada, the Law of Quebec goes to the extent to deal with the parentage of child born to a same sex couples. It provides that if both parents are women, the rights and obligation assigned by law to the father, in so far as they differ from the mother’s are assigned to the mother who did not give birth to the child.62 It does not exclude donor’s parentage rights; there parentage rights are similar to male partners.63

These are few of the remaining ancillary issues which may come up in near future. Law has to come out with answers which suit the society as well as scientific developments.

6. Future of Assisted Reproduction Technology (ART) and legal and ethical challenges:

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61 Status of Children Act, 1996, Sec. 5.14 and Sec. 10 C.
62 Civil Code of Quebec, 1991, Chapter I, Section 538.2
63 Ibid, Section 539.1
Discovery of human genomic knowledge and human cloning has presented diverse legal and ethical challenges before the society. These challenges are about how to make use of these technologies in human affairs ethically, legally, and socially acceptable. As far as knowledge of human genome is concerned, one major group of issues is ownership and control rights in the genome. Researchers need access to human Deoxiribo Nucleic Acid (DNA) and patient's medical records to identify genes and to develop drugs and treatments based on the Intellectual Property Rights (IPR) in genes or gene products. At the same time, the privacy rights of individuals in their bodily tissue, DNA and medical records are demanding strong protection.

The use of genomic knowledge in reproduction shows how socially and morally complicated genomic applications can be. Because genes are inherited system of information passed on to progeny, genomic knowledge increases the ability to predict or even control the gene offspring. Whether it would be ethical as well as legal to allow using human genome information to rewrite or engineer the genetic code of offspring? Such issues are to be resolved by society before permitting any use of knowledge of human genome.64 The most important issue related to these technologies is that whether by using these technologies we are playing with the almighty? As these technologies may be used even to create super humans, fattest women or man on earth, similarly in creation of even the monster. So question arises that what should be the limit of the use of these technologies? To whom it should be left to decide that what use should be permitted and what should not be permitted?

As far as cloning is concerned, the first issue is that whose clone should be allowed to make? Whether cloning be allowed for everyone and for whatever purpose they want, or it should be restricted to very limited purposes? Whether reproductive cloning be allowed or not? Whether such technologies should be

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allowed to relieve a woman from suffering and constrains of pregnancy?65 Before permitting any use of these technologies, such questions are to be answered. If a free market system is adopted then it must be considered that what type of society is to be created. Whether a society in which there is class segregation not only on the basis of economics but also on the basis of genetic superiority and inferiority would be beneficial for humanity? When genetically improved babies would be allowed to take birth just only because of their demand in society then such segregation of society can be easily visualized. But if only the use of these technologies is allowed to treat genetic deformity or diseases then definitely it would be in favour of humanity.

As far as Assisted Reproduction Technology (ART) is concerned, the purpose of these technologies is to provide infertile couples a chance to have their own genetically related children. Reproductive cloning can also be used in future to reach such goal. The most important issue related to reproductive cloning is the parentage of child. Since there is only one genetic parent in cloning, so question may arise as to who is father or who is the mother of the child. These technologies are in developmental stage, and this development goes on and on. So there is need to monitor the clinics or institution where such technologies may develop and used. Monitoring must be continuous and they must regulate the function of such clinics and institutions by some sort of guidelines which can be altered by them from time to time in response to scientific developments taking place around the world.

Reproductive cloning and reproductive technologies are capable enough to allow the misuse in a way which may be harmful to society. Similarly it has raised doubts over the protection of right to privacy of the individuals. So the protection of right to privacy is important challenge in era of biotechnological advancement. These technologies may create a new type of consumerism, human cells and genetic materials may become subject matter of sale and

65 Available at http://www.eubios.info/E.J.135.htm (Last visited 25/12/2013)
purchase. Similarly if parents will be allowed to effectively choose the genes of their children then perhaps they will be increasingly blamed for wrong choices. Such blame may be from the side of society, law and order maintaining institutions and also from the children themselves. Parent may also be held liable up to some extent for the wrong done by the child. In that situation, our family laws and criminal laws have to be modified to very large extent.

The development of these new technologies will not only enhance human control on reproductive choices and human genetics, but also poses many legal and ethical challenges before the society. These challenges must not be taken casually and before taking any step forward with these technologies its impact on society must be evaluated. These technologies require a strict control and regulation in the hands of a centralized body which can monitor the institutions and clinics where these technologies may be used and improved further.

6.1 Position in Developed Countries:

6.1.1 United States: In the US, the Food and Drug Administration, and Centre for Biologics Evaluation and Research have authority over cloning and gene transfer technologies in human.\textsuperscript{66} The National Institute of Health’s Human Embryo Research Panel has developed a science policy report, in which it has observed that in certain areas involving preimplantation human embryo research may be permitted within a framework of stringent guidelines.\textsuperscript{67} The Human Cloning Prohibition Act, 2001 was passed by House of Representatives. The Act makes it unlawful to:

- perform or attempt to perform human cloning,
- participate in an attempt to perform cloning, or
- receive the product of human cloning for any purpose.


\textsuperscript{67} Available at http://ospp.od.nih.gov/pdr/volume1-revised.pdf (Last visited on 23/09/2013)

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The Act also imposes penalties of up to 10 years of imprisonment and not less than $100000 penalty for breaking the law. This Act never became law, as it was never passed by senate. Again in 2003, the same Act was passed by the House of Representatives but again was not acted upon by senate. In 2007, another bill the Human Cloning Prohibition Act was introduced in the House of Representatives but defeated in the house. So yet there is no federal legislation to prohibit cloning. As far as the state laws are concerned, 15 states have laws pertaining to human cloning. California banned reproductive cloning or cloning to initiate pregnancy in 1997. Since then Arkansas, Connecticut, Indiana, Iowa, Maryland, Massachusetts, Michigan, Rhode Island, New Jersey, North Dakota, South Dakota and Virginia have banned reproductive cloning.68

6.1.2 Australia: The National Health and Medical Research Council, Australian Health Ethics Committee have formulated Ethical Guidelines on Assisted Reproduction Technology (ART), 1996 prohibiting the use of human embryo except for approved In-vitro Fertilization (IVF) programs and approved research into the potential for embryonic stem cells to replace parts of living bodies. The House of Representative’s Standing Committee had recommended in 2001 that reproductive cloning be banned but that stem cell research should be allowed to continue under a regulatory regime.

Further, the Common Wealth Gene Technology Act, 2000 prohibits the cloning of whole human beings. The Prohibition of Human Cloning Act, 2002 prohibits reproductive and therapeutic cloning, and trade in human eggs, sperm, or embryos. The Research Involving Human Embryos Act, 2002 allows for regulated use of small number of unwanted In-vitro Fertilization (IVF) embryos in approved research programmes. State and territory governments are also

68 Available at http://www.ncsl.org/programrns/cloning/health/genetics/rt-shcl.htm (Last visited on 12/04/2013)
introducing complementary legislation to provide nationally consistent regulation of human cloning.69

6.1.3 Canada: In Canada, human cloning is banned by Sec. 5 of the Assisted Human Reproduction Act, 2004 which provides that, "No person shall knowingly create a human clone by using any technique, including therapeutic cloning". But it permits research using stem cells derived from embryos. In addition, this Act allows researchers to use embryos left over from In-vitro Fertilization (IVF) treatments to create stem cells. It bars payment to donor of the sperm, egg or whole embryo.

6.1.4 United Kingdom (UK): In UK the embryonic cell research or any use is regulated by the Human Fertilization and Embryology Act, 1990. Human cloning for therapeutic purposes is permitted in the UK. The first license to create human embryonic stem cells using cell nuclear replacement was granted to "New Castle Centre for life" for one year. Thus UK is the first country in the world to permit regulation of these techniques.70

6.2 Response of International Organizations: In 1997, The European Union passed the Convention on Human Rights and Biomedicine with the purpose to protect the dignity and identity of all human beings in respect to the application of biology and medicine. Art. 2 of the Convention declare: That the interest and welfare of the human being shall prevail over the sole interest of society or science”. Art. 11 prohibit discrimination on ground of his or her genetic heritage. Art. 12 permit tests to predict genetic disease or to identify carrier of a gene responsible for genetic disease. Art. 13 provide that an intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes. Art. 18 prohibited in-vitro creation of human embryos for research purposes.

69 Available at http://www.biotechnology.gov.au/inde.cfmievent (Last visited on 27/03/2012)
70 Available at http://www.out-law.com/page-4796 (Last visited on 03/04/2012)
In the same year, United Nations Educational, Scientific and Cultural Organization (UNESCO) Bioethics Committee drafted Universal Declaration on the Human Genome and Human Rights, 1997 which was adopted on 11 November 1997 by 186 member states. This Declaration has covered almost all areas of cloning. But it also prohibited reproductive cloning. The principles mentioned in the declaration cannot take shape unless the states assume their role. On 8 March 2005, the UN Declaration on Human Cloning was adopted.

By this declaration on Human cloning state parties are called upon to:

- adopt all measures necessary to protect adequately human life in the application of life sciences;
- prohibit all forms of human cloning inasmuch as they are incompatible with human dignity and the protection of human life;
- adopt the measures necessary to prohibit the application of genetic engineering techniques that may be contrary to human dignity.\(^7\)

In India currently there is not any legislation to regulate Assisted Reproduction Technology (ART) and In-vitro Fertilization (IVF) and is frequently being used by In-vitro Fertilization (IVF) clinics. The Indian Council for Medical Research (ICMR) guidelines of 2005 which was revised in 2010 is only recommendatory. It is submitted that all these developments in the field of Biotechnology requires a statutory body for monitoring and strict regulation in India. There are different personal laws based on religions in India. These personal laws prohibit marriage in certain relations. These relations are incestuous relations and donation of gamete to a couple with whom a person cannot marry, raises a controversial issue before our law framers, which must be answered and the only way is the need of legislation or by amendments in old personal laws should be made to cope with these advanced technologies.

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