**Title: Embryonic Stem Cell Research: Ethical Issues**

**Author: Dr. Sufiya Ahmed, Assistant Professor, Department of Law, School for Legal Studies, Babasaheb Bhimrao Ambedkar University, Lucknow.**

**Address: Department of Law, School for Legal Studies, Babasaheb Bhimrao Ambedkar University, Lucknow, 226025**

**Email: sufi.bbau@gmail.com**

**Mobile: 8765584209**

**Embryonic Stem Cell Research: Ethical Issues**

***Abstract***

*The issue of embryonic stem cell research has raised considerable public controversy in many countries around the world. It raised a number of social, political, religious, moral and ethical issues as it involves killing or destroying of human embryos for the purpose of stem cell research. The stem cell controversy arises from the destruction of human embryos which is morally unacceptable if we consider embryo as a human being. The patenting of stem cell occur separate issue of granting patentability whether to product or process. The regulatory frameworks around the world related to embryonic stem cell research are not uniform as few countries allow it and few allow it with certain conditions; whereas few countries restrict the research. In India there is no law to regulate embryonic stem cell research but there are some guidelines issued by the Department of Biotechnology and Indian Council of Medical Research which are non-binding in nature. The aim of this paper is to critically analyze the socio-ethical issues arising out from the embryonic stem cell research as well as to analyze the present regulatory framework in India.*

**Keywords:** embryo, stem cell research, ethical issues, regulation, patent.

**Introduction**

Recent advances in stem cell biology have now made it conceivable that human eggs or sperm could potentially be derived from pluripotent stem cells or direct reprogramming of somatic cells.[[1]](#footnote-1) Embryonic stem cell research has been source of ethical, legal, and social controversy since the first successful culturing of human embryonic stem cells in the laboratory in 1998. The controversy has slowed the pace of stem cell science and shaped many aspects of its subsequent development.[[2]](#footnote-2) In the November 6, 1998 issue of the journal Science, James Thomson, a professor at the Wisconsin Regional Primate Research Center at the University of Wisconsin, reported he had developed the first line of hESC.[[3]](#footnote-3)

Stem cell research and therapy in India are rapidly growing fields. Currently, there are over 40 institutions and hospitals involved in stem cell research.[[4]](#footnote-4) Government policies in India are supportive of stem cell science and, keeping in view its potential therapeutic application, both basic and translational research is being promoted by the government in various institutions, hospitals and industry.[[5]](#footnote-5) The regulatory framework related to stem cell research includes ICMR‑DBT draft guidelines on stem cell research, and the CDSCO draft on compensation towards injury due to participation in clinical research. The department of biotechnology and Indian Council of Medical Research published the guidelines for stem cell research and therapy in November 2007 which was modified in 2017, addressing the ethical, scientific, legal and policy issues.[[6]](#footnote-6)

**Creating Human Embryo for Research**

Stem cells are undifferentiated biological cells that can differentiate into specialized cells and can divide (through mitosis) to produce more stem cells. They are found in multi-cellular organisms. They have the remarkable potential to develop into many different cell types in the body especially during early life and growth of an individual. In addition, they also serve as a sort of internal repair system in many tissues, to replenish other cells as long as the person or animal is still alive.[[7]](#footnote-7) In general, the stem cells can be divided into three categories: embryonic stem cells; umbilical cord stem cells and adult stem cells. The embryonic stem cell (ESC) is the ‘mother’ of all other cell types in the body and is derived from early stage of the human embryo, i.e. blastocyst. Blastocyst formation takes place after four days of fertilization. The blastocyst has an outer layer of cells while inside it has a hollow sphere with a cluster of cells called the inner cell mass. These inner mass cells are pluripotent in nature and may undergo further specialization into stem cells and give birth to cells having a particular function. These cells have the capability to turn into different types of tissues in the human body.[[8]](#footnote-8) Embryonic stem cells are of two types; pluripotent or totipotent. They have ability to become any type of cell found in the human body. Thus, stem cells from embryos have many practical use and applications. A stem cell is capable of renewing itself and developing into specialized cells. Since these cells can develop into a number of different tissues, scientists foresee many different stem cell based therapies. Current research suggests that stem cell therapies might one day have many therapeutic benefits. Proponents of stem cell research suggest that stem cell-based therapies might “revolutionize” medicine and lead to many effective therapies for previously untreatable diseases.[[9]](#footnote-9)

One of the most clinically promising sources of stem cells is embryonic stem cells. However, in the case of human beings, this process includes a major ethical issue: at the current moment, they cannot be obtained without causing the destruction of a human embryo. This fact makes their use extremely problematic for those who consider a human embryo morally equivalent to an adult human being.[[10]](#footnote-10) The study of embryonic stem cells would likely lead to a better understanding of fundamental processes in embryonic development. Embryonic stem cell research might also contribute to the exploration of the effects of chromosomal abnormalities in early development.[[11]](#footnote-11)

In fertility clinics, ART generally begins with ovulation via hormonal stimulation followed by oocyte retrieval for IVF. In cases of male infertility, the use of intracytoplasmic sperm injection (ICSI) is often required to produce viable embryos with one or a few sperm. Following fertilization, embryos are cultured, generally for 3–5 days, and one or more is selected for transfer to the uterus. Remaining preimplantation embryos are then either stored under cryopreservation for future embryo transfer to a patient or discarded. Following successful pregnancies, cryopreserved embryos may subsequently be discarded, given to other prospective parents, or donated to research.[[12]](#footnote-12) Embryonic stem cells used to develop cell lines can be derived from a number of different sources. Embryonic stem cells can be derived directly from early stage embryos. Fertilized zygotes are developed into blastocysts that are then dissected for their totipotent stem cells. Currently, many countries have formulated legislation precluding the creation of human embryos solely for research purposes.[[13]](#footnote-13)

**Ethical Issues**

The key distinction in the debate surrounding embryo research appears to be between the use of an embryo with the intention of achieving a successful pregnancy leading to a healthy baby, and its use for other reasons. Those who are opposed to all research involving human embryo argue that procedure which lead to the destruction of the embryo or which make it unsuitable for transfer to and should not be permitted in any circumstances. According to them, that research cheapens the act of procreation and turns embryos into commodities.[[14]](#footnote-14) Genetic manipulation may be done to correct the prospects of a child that may be born with some abnormalities. At the other extreme, procedures that do not damage the embryo, or that are actively beneficial to it, do not give the cause for concern even though such procedures may form part of what some would regard as a programme of research. In addition to the ethical issues that surround all clinical research there are additional facets added to stem cell research due to the use of human embryos, manipulations and modifications**.[[15]](#footnote-15)**

**Moral status of Embryo**

Opponents to ES cell research hold that the human embryo has the moral status of a human being from its creation. Therefore, the destruction of embryos for the benefit of others violates the embryo’s rights and consequently is illicit. At the other end of the spectrum, it is believed that the moral status of an early human embryo is equivalent to any other cell in the human body and therefore there is no need for any protection. In between these opposing views, there is the opinion that a human embryo has neither the full moral status of a person nor an absolute right to live. In this context, the protection demanded for an embryo is not absolute and might be weighed against the benefit of research purposes.[[16]](#footnote-16)

The case on disposition of embryos frozen during the fertility treatment is *Davis v. Davis*. In this case a dispute arose between a divorcing couple about the disposition of seven frozen embryos produced from the husband’s sperm and the wife’s ova. The trial court portrayed the embryos as children and granted temporary custody of the frozen embryos with the divorcing wife. The appellate court decided the status of the embryos as resting somewhere between property and body organs. Finally the state’s highest court concluded that the embryos, while neither persons nor property, enjoyed a special status because of their potential for human life.

**Embryonic stem cell patenting**

In addition to economical benefits, a numbers of intellectual properties and patented protocols will be one of the key indicators for stem cell research strength and potential.[[17]](#footnote-17) The main ethical controversy of human embryonic stem cell patents lies in ‘the special moral and cultural significance attached to the human embryo. This moral concern attends not only to debates about the innate value of human life in the context of abortion, but also to the potential diminution of the status of the embryo from person to ‘thing’ through instrumental use or exchange.’[[18]](#footnote-18) The European Patent Office’s (EPO) rejection to grant a patent to the Wisconsin Alumni Research Foundation (WARF) on hESC due to the fact that they were derived from embryos “marks a significant divergence in patent policy between the EPO and the world’s other major patent issuing bodies, notably the US Patent and Trademark Office (USPTO).”[[19]](#footnote-19)

It has been noted that the number of patents applications in stem cell research has increased by 300% over the past few years.[[20]](#footnote-20) Cell lines and genetically modified single cell organisms have long been considered patentable in many countries. To date, 2000 patents applications have been filed worldwide wherein inventions involving human and nonhuman stem cells are claimed. Of these, 500 applications refer to embryonic stem cells.[[21]](#footnote-21)

In the United States, laws of nature, natural phenomena, and abstract ideas are not patent-eligible subject matter. With respect to the stem cells and their use in the field of regenerative medicine, the U.S. Patent and Trademark Office have recognized inventions involving stem cells as patent-eligible subject matter.[[22]](#footnote-22) On June 13, 2013, the U.S. Supreme Court given the decision in *Association for Molecular Pathology, et al., Petitioners v. Myriad Genetics, Inc., et al.[[23]](#footnote-23),*addressing the controversial question of whether DNA is patent-eligible subject matter under 35 U.S.C. § 101. Drawing a line between two different forms of DNA molecules, the Supreme Court held that isolated DNA is an unpatentable product of nature while cDNA is a non-naturally occurring genetic sequence and is patentable under the statute.

**Regulatory Mechanism in India**

India has allowed establishment of new human embryonic stem cell lines with spare, supernumerary embryo with prior approval of the Institutional Committee for Stem Cell research and Therapy (IC-SCRT) and Institutional Ethics Committee (IEC) provided appropriate consent is obtained from the donor as per the draft guidelines.[[24]](#footnote-24) In India, the relationship between the supply of embryos for hESC research and the political and cultural context is a complex one. India's IVF clinics are an established source of embryos for research to which foreign scientists come for supplies. However, in the wake of the setting up of the ESC line research at Reliance Life Sciences Laboratory and the National Centre of Biological Sciences in 2001 and its associated publicity, the government announced a “crack down” on the trade to counter the international view of India as “an embryo surplus” nation.[[25]](#footnote-25) But without legal backing for the Guidelines, Indian stem cell scientists feel free to consult their own consciences and make their own decisions.[[26]](#footnote-26)

**The aim and scope of the DBT-ICMR guidelines**

Section 2 of the DBT-ICMR guidelines says that these guidelines are applicable to all stakeholders including individual researchers, organizations, sponsors, oversight/regulatory committees and all others associated with both basic and clinical research involving any kind of human stem cells and their derivatives. The DBT-ICMR guideline focuses on: 1. Monitoring mechanism and regulatory pathway for basic, clinical research and product development based on categories of research and level of manipulation. 2. Procurement of gametes, embryos and somatic cells for derivation and propagation of any stem cell lines, their banking and distribution. 3. Other important areas like international collaboration, exchange of cell/lines and education for stakeholders and advertisement.[[27]](#footnote-27) The principal upon which the DBT-ICMR guideline is based on is stated under section 3 which states: Research on human participants involving cells and tissues derived from human embryos, fetuses or any other sources must safeguard human rights, safety, dignity, and fundamental freedom.

**Ethical and Scientific Consideration**

**Informed Consent:**

Section 4.1 of the DBT-ICMR guideline strictly states that donors should neither be exploited nor commoditized. Regarding informed consent of the donor, following information should be given to donor:

1. The donor must be informed about the need for screening of transmittable diseases (about which s/he may or may not be aware of) and of any other risk factors including possible genetic disorders as is practiced for blood and other organ/tissue/cells donation.
2. Further, procedural risks involved during collection of organ/tissue/ cells (e.g. ovum, bone marrow etc), under local or general anesthesia should be adequately explained. These details must be included in the information sheet and should be understood by the donor in his/ her preferred language.
3. The donor shall also be informed that under exceptional circumstances, cell lines/products may be generated from the donated material and that these may be banked and shared with other scientific groups.
4. The cell lines/products may also undergo genetic manipulation and have the potential for commercialization. In the latter event, the Intellectual Property Rights (IPR) of the biological material will not vest with the donor. However, if commercialization brings any benefits, say financial, efforts should be made to pass on the same to the donor/community wherever possible.
5. The donors should be made aware that they may be contacted in future for any specific requirements.

**Scientific Considerations:**

Section 4.2 of the DBT-ICMR guideline makes provisions regarding scientific risks. It states that appropriate measures should be taken and proper investigations performed to ensure that the stem cell derived product is safe for human application. The guideline says under section 4.2.3 in very strict terms that the commercial use of stem cells as elements of therapy is prohibited. It must be emphasized that no stem cell administration to humans is permissible outside the purview of clinical trials.

**Stem Cell Research**

Section 8 of the DBT-ICMR guideline categorizes the stem cell research into three categories: permissible, restrictive and prohibited.

**Permissible Areas of Research** include, *In vitro* studies using stem cells isolated from tissues can be done with prior approval of IC-SCR and IEC And Establishment of new human ESC lines from spare embryos or iPSC lines from fetal/adult somatic cells or SSCs from fetal or adult tissues, with prior approval of the IC-SCR and IEC.[[28]](#footnote-28)

**Restrictive Areas of Research** include, basic and translational research activities requiring additional arm of oversight/monitoring due to contentious issues involved. Such activities needs close supervision and strict adherence to the guidelines. Creation of human pre-implantation embryos by In vitro fertilization (IVF), Intracytoplasmic Sperm Injection (ICSI) , Somatic Cell Nuclear Transfer (SCNT) or any other method with the specific aim of deriving ESC lines for any purpose.[[29]](#footnote-29)

**Prohibited Areas of Research[[30]](#footnote-30)**

Under section 8.3 of the DBT-ICMR guideline stem cell research in the following areas is prohibited:

1. Research related to human germ line gene therapy and reproductive cloning.

2. In vitro culture of intact human embryos, regardless of the method of their derivation, beyond 14 days of fertilization or formation of primitive streak, whichever is earlier.

3. Clinical trials involving xenogeneic cells.

4. Any clinical research on Xenogeneic-Human hybrids.

5. Use of genome modified human embryos, germ-line stem cells or gametes for developmental propagation.

6. Research involving implantation of human embryos (generated by any means) after in vitro manipulation, at any stage of development, into uterus in humans or primates.

7. Breeding of animals in which any type of human stem cells have been introduced at any stage of development, and are likely to contribute to chimeric gonadal cells.

**International Regulatory Mechanism**

Legislation governing hESC research varies from country to country. Some countries like India, Israel, Singapore, Sweden, Australia, United Kingdom and other European countries have relatively liberal and research-favourable regulatory policies, while others are still struggling to draft regulatory policies.[[31]](#footnote-31)At the present moment, there are more than 700 companies worldwide working in some way on regenerative medicine, that have produced a significant number of therapeutical products, benefitting thousands of patients.[[32]](#footnote-32) On an international level, there are also worries that stringent regulations governing how stem cells can be obtained could lead to the importation of tissue or cells from countries where the rules are less strict. This was discussed at the 5th World Congress of the International Association of Bioethics in London (21–24 September 2000).[[33]](#footnote-33) The Food and Drug Administration in the United States has been issuing guidance periodically for development of human cells, tissues, and cellular and tissue-based products (HCT/Ps) for clinical use utilising a tiered, risk-based approach.[[34]](#footnote-34)

The Human Fertilization and Embryology Act 1990 of U.K. allow embryo research after the authorization of the authority. The research licence allows for the creation and use of in vitro embryos for certain specific purposes. Para 3 of sch. 2 to the Act sets out the type of projects for which these licences may be granted:

1. The promotion of advances in the treatment of infertility.
2. Increasing knowledge about the causes of congenital disease.
3. Increasing knowledge about the causes of miscarriage.
4. Developing more effective contraception techniques.
5. Developing methods of detecting the presence or absence of gene or chromosome abnormalities before the implantation of an embryo.

It is a duty of the authority to monitor and review information on embryos as well as of the treatment services being provided by reason of the granting of a license.[[35]](#footnote-35) With regard to cloning, the Authority might consider treatment licences which involve the use of cloning techniques, but this would have to be combined with a suitable redefinition of embryo.

In the U.S., the government policies shaped over the last few decades for regulating embryonic stem cell research. Since 1996, U.S. appropriations bills have included the Dickey-Wicker Amendment as a rider that explicitly prohibits the use of government funds for the creation of human embryos or for research in which human embryos were destroyed or discarded. For the purpose of National Institutes of Health (NIH) funding, an embryo is defined as any organism not protected as a human subject under 45 Code of Federal Regulation (CFR). Since 1999, the Department of Health and Human Services (HHS) has consistently interpreted this provision as not applicable to research using hESC, because hESC are not embryos as defined under Section 509. This long-standing interpretation has been left unchanged by U.S. Congress. These guidelines therefore recognize the distinction, accepted by Congress, between the derivations of stem cells from an embryo that results in the embryo's destruction, for which federal funding is prohibited, and research involving hESC that neither involves an embryo nor results in an embryo's destruction, for which federal funding is permitted. Following President Barack Obama's Executive Order 13505 of March 9, 2009, the NIH issued further guidelines for funding hESC research. The guidelines allowed for funding of research using hESC derived from embryos created using *in vitro* fertilization for reproductive purposes and that were no longer needed for such purposes, with the caveat that the research should have scientific merit and that the embryos were donated after proper informed consent was obtained from the donor(s).[[36]](#footnote-36)

**Conclusion**

Embryonic Stem cell research is a very sensitive issue not only socially but ethically also. The destruction of human embryos for solely research purpose is morally unacceptable. The granting of patent to stem cells is also very controversial. The DBT-ICMR guidelines are not binding and there is a need to pass a proper legislation to regulate human embryonic stem cell research in India. Any policy regulating the use of human embryo for research purpose should take into consideration the following points:

1. The legal-moral status of human embryo should be clearly defined.
2. The destruction of human embryo solely for research purpose should not be allowed.
3. The unused embryos should not be donated for research without the consent of the donor.
4. The patenting of stem cell research should be banned.
5. Genetic manipulation of human embryo should not be permitted.
6. Only those researches which are of therapeutic purposes should be allowed.

1. Tetsuya Ishii, Renee A Reijo Pera, and Henry T. Greely, Ethical and Legal Issues Arising in Research on Inducing Human Germ Cells from Pluripotent Stem Cells, Cell Stem Cell 13, August 1, 2013 ª2013 Elsevier Inc. available at <https://www.ncbi.nlm.nih.gov/pubmed/23910081> [↑](#footnote-ref-1)
2. J.A. Robertson, Embryo Stem Cell Research: Ten Years of Controversy , (38 J.L. Med. & Ethics 191, 2010) pp. 191-203, p.191, available at: http://heinonline.org. [↑](#footnote-ref-2)
3. Aurora Plomer, Kenneth S. Taymor, and Christopher Thomas Scott, Challenges to Human Embryonic Stem Cell, Cell Stem Cell, [Volume 2, Issue 1](https://www.sciencedirect.com/science/journal/19345909/2/1), 10 January 2008, Pages 13-17, available at <https://www.sciencedirect.com/science/article/pii/S1934590907003220> [↑](#footnote-ref-3)
4. S Dey, “Selling Stem Cells” available at

   <http://www.expresspharmaonline.com/20071215/market01.shtml> cited in *Prasanna Kumar Patra and Margaret Sleeboom-Faulkner*, “Bionetworking: Between Guidelines and Practice in Stem Cell Therapy Enterprise in India” (2010) 7:2 *SCRIPTed*  [↑](#footnote-ref-4)
5. Prasanna Kumar Patra and Margaret Sleeboom-Faulkner, “Bionetworking: Between Guidelines and Practice in Stem Cell Therapy Enterprise in India” (2010) 7:2 SCRIPTed [↑](#footnote-ref-5)
6. C. S. Mukhopadhyay, Jayanti Tokas1 and P. D. Mathur, Prospects and Ethical Concerns of Embryonic Stem Cells Research-A Review, Veterinary World, 2011, Vol.4(6): 281-286, DOI:10.5455/vetworld.4.281 [↑](#footnote-ref-6)
7. Dr. Mohammadi Begum, Dr. Faizan Ahmed Khan, Ethical Issues in the Stem Cells Research- An Updated Review, International Journal of Medical Science and Clinical Inventions 4(2): 2662-2669, 2017 [↑](#footnote-ref-7)
8. Alka Sharma, Stem Cell Research in India: Emerging Scenario and Policy Concerns Scenario and Policy Concerns, 2006, Asian Biotechnology and Development Review Vol. 8 No. 3, pp 43-53 available at <http://www.ris.org.in/images/RIS_images/pdf/article4_v8n3.pdf> [↑](#footnote-ref-8)
9. Miriam Brouillet, Leigh Turner, Bioethics, Religion, and Democratic Deliberation: Policy Formation and Embryonic Stem Cell Research, *Hecforum, 2005; 17(1): 49-63* available at <https://link.springer.com/content/pdf/10.1007/s10730-005-4950-8.pdf> [↑](#footnote-ref-9)
10. De Miguel-Beriain, The ethics of stem cells revisited, Advanced Drug Delivery Reviews 82–83 (2015) 176–180 [↑](#footnote-ref-10)
11. Miriam Brouillet, Leigh Turner, Bioethics, Religion, And Democratic Deliberation: Policy Formation And Embryonic Stem Cell Research, Hecforum, 2005; 17(1): 49-63 [↑](#footnote-ref-11)
12. Tetsuya Ishii, Renee A. Reijo Pera, and Henry T. Greely, Ethical and Legal Issues Arising in Research on Inducing Human Germ Cells from Pluripotent Stem Cells, available at <http://www.cell.com/cell-stem-cell/abstract/S1934-5909(13)00313-5> [↑](#footnote-ref-12)
13. Baylis F. HESC lines: The ethics of derivation. Journal of Obstetric Gynecology of Canada 2002; 24(2): 159-163. cited in Miriam Brouillet, Leigh Turner, Bioethics, Religion, and Democratic Deliberation: Policy Formation and Embryonic Stem Cell Research, Hecforum, 2005; 17(1): 49-63 available at <https://link.springer.com/content/pdf/10.1007/s10730-005-4950-8.pdf> [↑](#footnote-ref-13)
14. [↑](#footnote-ref-14)
15. Mittal S. Stem cell research: The India perspective. Perspect Clin Res 2013;4:105-7. available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3601694/> [↑](#footnote-ref-15)
16. Gorka Orive, Rosa M. Herna´ ndez, Alicia R. Gasco´ n, Manoli Igartua and Jose´ Luis Pedraz, Controversies over stem cell research, TRENDS in Biotechnology Vol.21 No.3 March 2003 109 available at <http://www.cell.com/trends/biotechnology/pdf/S0167-7799(03)00003-9.pdf> [↑](#footnote-ref-16)
17. Sorapop Kiatpongsan, Intellectual Property and Patent in Stem Cell Research Era, J Med Assoc Thai Vol. 89 No. 11 2006, available at <https://pdfs.semanticscholar.org/efcb/b80a066f9041031b3cbbd7b0c44abe49d261.pdf> [↑](#footnote-ref-17)
18. G. Bahadur & M. Morrison, Patenting Human Pluripotent Cells: Balancing Commercial, Academic and Ethical Interests, (Human Reproduction, Vol.25, No.1, 2010) pp. 14–21, p. 15, available at: http://humrep.oxfordjournals.org/. [↑](#footnote-ref-18)
19. Ibid [↑](#footnote-ref-19)
20. Caulfield TA. From human genes to stem cells: new challenges for patent law? Trends Biotechnol 2003; 21: 101-3 cited in Sorapop Kiatpongsan, Intellectual Property and Patent in Stem Cell Research Era, J Med Assoc Thai Vol. 89 No. 11 2006, available at <https://pdfs.semanticscholar.org/efcb/b80a066f9041031b3cbbd7b0c44abe49d261.pdf> [↑](#footnote-ref-20)
21. Ibid. [↑](#footnote-ref-21)
22. [Nicholas A. Zachariades](https://www.ncbi.nlm.nih.gov/pubmed/?term=Zachariades%20NA%5BAuthor%5D&cauthor=true&cauthor_uid=24304078),  Stem Cells: Intellectual Property Issues in Regenerative Medicine, [Stem Cells Dev](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3883125/). 2013 Dec 1; 22(Suppl 1): 59–62. available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3883125/> [↑](#footnote-ref-22)
23. 569 U.S. \_\_ (2013). [↑](#footnote-ref-23)
24. Amit M Patil, Embryonic Stem Cell Research Ethical and Legal Controversies, J Indian Acad Forensic Med. April-June 2014, Vol. 36, No. 2 available at <http://medind.nic.in/jal/t14/i2/jalt14i2p188.pdf> [↑](#footnote-ref-24)
25. [Sanjay Mittal](https://www.ncbi.nlm.nih.gov/pubmed/?term=Mittal%20S%5BAuthor%5D&cauthor=true&cauthor_uid=23533992), Stem cell research: The India perspective, [Perspect Clin Res](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3601694/). 2013 Jan-Mar; 4(1): 105–107. available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3601694/> [↑](#footnote-ref-25)
26. Ibid. [↑](#footnote-ref-26)
27. Section 2, National Guidelines For Stem Cell Research, Indian Council of Medical Research & Department of Biotechnology, 2017 [↑](#footnote-ref-27)
28. Id, Section 8.1, [↑](#footnote-ref-28)
29. Id, Section 8.2, [↑](#footnote-ref-29)
30. Id, Section 8.3, [↑](#footnote-ref-30)
31. Alka Sharma, Stem Cell Research in India: Emerging Scenario and Policy Concerns Scenario and Policy Concerns, 2006, Asian Biotechnology and Development Review Vol. 8 No. 3, pp 43-53 available at <http://www.ris.org.in/images/RIS_images/pdf/article4_v8n3.pdf> [↑](#footnote-ref-31)
32. De Miguel-Beriain, The ethics of stem cells revisited, Advanced Drug Delivery Reviews 82–83 (2015) 176–180 available at <https://www.ncbi.nlm.nih.gov/pubmed/25446134> [↑](#footnote-ref-32)
33. (http://www.uclan.ac.uk/facs/ethics/fifthcon. htm) cited in Kathryn Senior, Extending the ethical boundaries of stem cell research, TRENDS in Molecular Medicine Vol.7 No.1 January 2001, available at <http://www.cell.com/trends/molecular-medicine/abstract/S1471-4914(00)01870-0> [↑](#footnote-ref-33)
34. Food and Drug Administration, CFR-Code of Federal Regulations Title 21, Part 1271: Human Cells, Tissues, and Cellular and Tissue-Based Products, US Food & Drug Administration, 2014 available at (<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/> cfrsearch.cfm: accessed 12th January,2016) cited in Anjali Nagpal, Chris Juttner , Monica Anne Hamilton-Bruce, Paul Rolanc, Simon A. Koblar , Stem cell therapy clinical research: A regulatory conundrum for academia, Advanced Drug Delivery Reviews 122 (2017) 105–114 [↑](#footnote-ref-34)
35. Section 8 (a), The Human Fertilization and Embryology Act 1990 [↑](#footnote-ref-35)
36. Supra note 22. [↑](#footnote-ref-36)